UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	CIVIL ACTION NUMBER: 1:19-md-02875-RBK-JS
	ORAL ARGUMENT ON "MACRO" DISCOVERY ISSUES

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
Wednesday, November 20, 2019
Commencing at 10:09 a.m.

B E F O R E: **THE HONORABLE JOEL SCHNEIDER, UNITED STATES MAGISTRATE JUDGE**

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THE DEPUTY CLERK: All rise.

(OPEN COURT, November 20, 2019, 10:09 a.m.)

THE COURT: Good morning, everybody, please be seated. Welcome back to Camden.

We're on the record in the Valsartan MDL, Docket No. 19-2875. Whoever is going to speak today, if you could just state your name. Let's start with plaintiffs.

MR. NIGH: Daniel Nigh for the plaintiffs.

MR. SLATER: Good morning, Your Honor, Adam Slater for plaintiffs.

MR. HONIK: Good morning, Your Honor, Ruben Honik.

MS. WHITELEY: Good morning, Your Honor, Conlee Whiteley for plaintiffs.

MR. PAREKH: Good morning, Your Honor, Behram Parekh for plaintiffs.

MS. GOLDENBERG: Good morning, Marlene Goldenberg for plaintiffs.

MR. WILLIAMSON: George Williamson for plaintiffs.

MS. HILTON: Layne Hilton for the plaintiffs.

MR. GOLDBERG: Your Honor, Seth Goldberg for ZHP and the defendants.

MR. RUBENSTEIN: Good morning, Your Honor, Brian Rubenstein for Teva defendants and other defendants.

MR. REEFER: Good morning, Your Honor, Jason Reefer for Mylan and the other defendants.

THE COURT: Okay. This is what we have planned for today. This morning we'll hear oral argument on all of the, what I call macro discovery issues that you all have briefed. If things go according to plan, I'd like to take a relatively short lunch break and barring unforeseen circumstances, when you come back from lunch, you'll get rulings on all of the issues before the Court today.

It's the Court's desire and intent that these rulings will set the groundwork for your discussions over the next few weeks, for ultimate resolution on December 11, when we're dealing with what I call the granular issues, the request for production of documents.

After the Court reads its rulings into the record, Judge Kugler is available today, and I thought it would be a good idea if we meet with Judge Kugler. He's available for all of you if there's any questions or issues that you'd like to address with him.

So, if you'll just indulge me, let's get right into it. I have a few questions, I've read all the papers. I think I understand the issues. If we could just go through a couple of questions to get through the background and then we'll get to the nitty gritty.

Before we get into the issues in the Court's order, there was one issue I regret not putting into the order that came to my attention from reading the briefs. I just want to

raise it with the parties now. We're not going to decide it today, and that's the redaction issue. I'd like to hear from the parties on whether, one, it's appropriate to redact any of the core discovery that the Court ordered to be produced. I did not know that that had happened until I read the parties' briefs, and I'm especially concerned about the redactions about any correspondence sent to or received from the FDA. I don't know. I just don't know if it's appropriate.

So here's what I'd like to do. We're not going to decide the issue today. But what I'd like to do is resolve the issue on December 11th, set a date for simultaneous briefs. It's not that complicated of an issue.

Plaintiff, do you have just a guesstimate of -- are we talking about a lot of documents, a little number of documents, do you know?

MR. PAREKH: It's a significant number of documents, Your Honor.

THE COURT: Okay. Here's what I'd like you to do. I'd like you to identify, pick a number, 20 documents, 20 representative documents that you believe should be unredacted, identify them for the defendant.

I'm going to ask plaintiff what their submission to send the Court copies of what you receive, the unredacted document, and I'm going to ask the defendants to send -- I'm sorry, you got the redacted document and I'm going to ask the

defendants to send the Court the unredacted documents.

Defendants, you pick 20 documents that you think are representative of the appropriateness of the redactions, send the Court, of course identify them for the defendant, send the Court the unredacted copy and the redacted copy.

So the Court will have 20 representative documents from each side. I'm going to review those documents in camera to see if they should be unredacted, as representative of the entire scope, and you'll get the Court's ruling on December 11th.

So we're not dealing with a terribly complicated issue if we get together -- is there any reason -- can we do simultaneous briefs by December 4?

MR. SLATER: Yes.

THE COURT: All right. And make sure you identify fairly promptly the 20 documents you want defendants to produce to the Court for in-camera review. We'll get all those documents December 4 with the simultaneous letter briefs and you'll get the Court's ruling.

Plaintiffs, is that the only set of documents that you're concerned about redactions?

MR. PAREKH: Those are the only documents that we have at this point, so, yes. One point that we would like to bring up, though, and we've brought this to defendant's attention multiple times, is that we've never received a

privilege log with regards to the redaction documents, which is required under the ESI protocol and we still haven't.

THE COURT: Well, let me suggest this. Let's hold off on -- it wouldn't be a privilege log, it would be a redaction log.

MR. PAREKH: Redaction log, but it falls under the privilege log provision of the ESI protocol.

THE COURT: So let -- I would suggest you hold off on that because if the Court rules on December 11 that unredacted copies have to be produced, then that issue is moot. If the Court orders that they will stay redacted, then I assume the parties are going to comply with the agreed-upon Court order protocol. Okay?

I think -- now I remember what I was thinking of. I'm not sure, it might have been Teva -- it was either Teva or Mylan, but I think it was Teva, they reproduced redacted documents but agreed to produce unredacted documents with their document production. Am I right about that? Do you remember that?

MS. HILTON: Yes, Your Honor. Those represent -- Layne Hilton on behalf of the plaintiffs. Those represent e-mails that they produced in the course of core discovery which attached regulatory filings, and the e-mails were from the custodial file of a regulatory department chair, and they redacted the internal e-mail, but kept unredacted all of the

attachments.

THE COURT: But they agreed to produce unredacted copies.

MS. HILTON: Yes.

THE COURT: So why in the -- Teva, why in the world won't you just produce them now? Why do we have to wait?

MR. RUBENSTEIN: Your Honor, a point of clarification. They weren't redacted documents. They were just withheld. They were strictly internal communications that were withheld. The communications that went to the FDA were produced as part of the core discovery. What was withheld, not redacted, withheld, were the strictly internal communications within Teva.

THE COURT: So the internal communications were not sent to the FDA.

MR. RUBENSTEIN: Correct.

THE COURT: So your position is, now it's clarified, that that wasn't classically within the definition of core discovery, that's why you held off producing them.

MR. RUBENSTEIN: Correct, and we discussed it here and you agreed with us.

THE COURT: Okay. That's a little different than what was in the papers. So it wasn't redacted, it was just withheld, right?

MS. HILTON: Well, the functional -- if I may, the

functional practical implication was that we had an e-mail, the e-mail had a redaction box and then we had -- you know, we didn't know that this, you know, other than counsel telling us that it was an internal communication, but it attached, you know, 15 correspondences with the FDA, and so we didn't -- our -- functionally, it looked like a redacted document. That's what we saw.

THE COURT: Okay. Well, it's clarified now. You'll get the actual document with the production.

MR. SLATER: And, Judge, it ties in with one other issue we've been bringing up to the Court. We still do not have all of the documents that are referenced in the core discovery communications between the manufacturers and the FDA.

For example, they refer to documents that were provided to the FDA that we do not yet have. It's still -- it's something we've brought up multiple times just to let you know. We're still waiting for those things and it's going to come up during the course of the arguments, most likely, today.

THE COURT: These are documents that the Court already ordered to be produced.

MR. SLATER: Right.

THE COURT: Has it been brought to the attention what we're talking about? I haven't seen that anywhere.

MR. SLATER: No. We've mentioned it a couple times, but we were -- we keep -- we're assuming the defense, because we've talked to them about it, were going to make sure we had everything, and we have so much going on, now the rubber is hitting the road, so they have to complete the production of everything they gave the FDA.

THE COURT: Is it one company or more than one company?

MR. SLATER: It's multiple.

THE COURT: All right. Is there a reason why it hasn't been produced, Mr. Goldberg?

MR. GOLDBERG: Your Honor, assuming I'm understanding what Mr. Slater is referring to, some of the FDA documents refer to documents that were made available to the FDA in China and in India on inspections.

So the FDA documents that we've produced might say, see Exhibit 7. Exhibit 7 is still in China. It was something that was reviewed on the inspection, so whether it was in a room, whether it was in a lab, whether it was in some other part of the facility, when the FDA is doing their walk-through in China, there are documents they are looking at.

When we produced our documents in core discovery, I don't think we had that appreciation, so we produced everything that we had that we understood to be core discovery, the FDA communications.

At some point, plaintiffs raised the fact and it was only recently brought to our attention that there were exhibits referred to that weren't produced.

We discussed this in a meet and confer on November 8th, and we told plaintiffs, we will assemble those documents for you, and we intend to produce those.

I don't know how else to do it. The core discovery order was talking about readily available documents and certainly not documents that were someplace else in China.

MR. SLATER: And for obvious reasons, Your Honor, our view is the order was violated. These documents should have been produced. They're actually referenced in the documents that were produced. There could have been no ambiguity on the Court's order. Whatever they exchanged with the FDA or showed the FDA should have been produced, and what we keep getting told is, you have all this core discovery, you're ready to set search terms and custodianship, that's incomplete. There's some org charts that are not in our possession yet. There are some that are not fully translated yet, et cetera.

I just want as a background for the Court's consideration during the arguments today, to know this, that we're not armed with everything we're even supposed to have, which is still a small part of what we ultimately will need.

THE COURT: The documents, Mr. Goldberg, that we're talking about, is it fair to characterize them as documents

that were made available to the FDA for inspection that have not already been produced?

MR. PAREKH: Your Honor, just to clarify, it's our understanding that during the EIR process, the FDA gets a copy and takes with it a copy of those documents. They're not just looked at on-site, but a copy is actually produced and taken by the FDA, which is why we continue to maintain that those are communications that were given to the FDA.

THE COURT: Did you not receive those documents in response to your FOIA request? And if not, why not?

MS. WHITELEY: Your Honor, this is Conlee Whiteley speaking. And when we got the establishment inspection report, it's full of redactions and that's something the FDA does, but we believe these are documents that would normally not be redacted under our discovery rules and that we would want to get from defendants.

THE COURT: The redactions we're talking about, if we step back, I'm talking about the defendant's redactions, not the FDA's redactions.

MR. SLATER: Separate issue, different issue.

MS. WHITELEY: That's right, Your Honor.

THE COURT: All right. Mr. Goldberg, am I correct, could we characterize what we're talking about as documents that were either made available to the FDA for inspection or produced to the FDA?

MR. GOLDBERG: If they were produced to the FDA, they were produced to the FDA in China. It's not something that happened here. And so that's why when we produced the EIR reports or the 483s or whatever it is that referred to these documents, we had what we had in the U.S., we produced that. We were not sensitive to this issue, that there were documents that were made available by inspection.

THE COURT: So it's in the works.

MR. GOLDBERG: It is in the works, absolutely, yes, Your Honor.

THE COURT: Is ZHP the only party that this issue pertains to?

MR. SLATER: No.

THE COURT: Who else does it pertain to?

MS. HILTON: Your Honor, to the extent that any one was inspected by the FDA, they necessarily provided the FDA with documentation, and every single EIR produced by every single defendant to date lists, you know, at the end of the EIR -- and I'll refer you to Exhibit 1, you can see at the end of Exhibit 1, you'll see such a list of documentation that is provided. So every single inspection comes with an exchange of documents.

THE COURT: All right. So I just made a note about what we're talking about. Documents that were made available to the FDA for inspection and/or produced to the FDA during

their inspections of defendants', what, API manufacturing facilities?

MR. SLATER: And finished dose.

MS. HILTON: And finished dose manufacturing facilities.

THE COURT: Okay. All right. I'll clarify that that has to be produced. But based on what Mr. Goldberg represented, it sounds like this is in the works and plaintiffs are going to get these documents.

MR. SLATER: Just, Your Honor, one clarification on the wording. I can't stand here and tell you the only example of a document that we don't have that was referenced in a core discovery document is something that was made available during inspection. So we just wouldn't want to --

THE COURT: Or produced.

MR. SLATER: Yeah, I mean it could be during their correspondence or their back and forth, outside of the inspections or following the inspections. We just don't want it to be -- cut out something that may have occurred in the course of their back and forth.

MR. RUBENSTEIN: Your Honor, just a small point of clarification. During the core discovery process, EIRs, inspection reports, things like that, were not required to be produced by the finished dose manufacturers. So it was just the API manufacturers at this point.

THE COURT: That's one of the issues for today, isn't it?

MR. RUBENSTEIN: It is.

THE COURT: All right. Okay. So indulge me. I just have a few questions and we'll get into the nitty gritty.

First, plaintiffs. One of the themes that seems to be running through defendants' papers is that the die has already been cast on the cause of this contamination, when it started. Defendants represent in their briefs that there was no test to identify these contaminants until July 18, and based on that, defendants, you know, then go on to their argument, and I just want to clarify.

If plaintiffs agree to certain prevailing theories, that's great, that will help us with the scope of discovery, but I'm not sure that's the case. Can you speak to that?

MR. SLATER: Right. First of all, Your Honor, there's evidence that we've presented to the Court already on this briefing that contamination with nitrosamines predated the manufacturing change to what we're going to call the third methodology, the one that was the last one they were using --

THE COURT: So are we talking now just about one party or all API manufacturers?

MR. SLATER: Well, I'm talking -- I'm starting out in the context of ZHP, because we have more information about what happened there, of necessity we do. We have evidence

that the contamination predated this change.

So we're not at all convinced that this is such a simple case where, oh, we made a manufacturing change and it started at that point, because we have evidence that contamination with nitrosamines predated that date, which is why the starting point for the effective date, as you're going to get to, needs to be pushed back to the beginning.

No. 2, the suggestion that no test existed until after this came to light that could have disclosed it, is -- I think I learned this word in law school -- silly, because we know how ZHP found out and how this was discovered, which was when Novartis looked at their API, which was going to be a finished dose downstream user of their API and found the problem and sent it back and said, you have a problem here.

So, you know, that covers a lot of issues. You have a finished dose where a downstream entity actually discovering the problem, which shows they actually do things beyond just cobble it together and shove it into a box, because they have obligations under the regulatory scheme to look.

So their suggestion that this couldn't have been discovered makes absolutely no sense. There was testing that was done, there was so-called ghost peaks being seen for a long time that were being ignored. We believe that we're going to be able to show that there was plenty of evidence that if they didn't actually know it, which there's reason to

believe that they did know and kind of just kept going, but there was certainly plenty of evidence that it could have been figured out if they just looked at the test results and actually evaluated them appropriately.

THE COURT: So this is my question, and we're not going to solve the issue of who's right and who's wrong, but I just want to clarify for the record whether or not a representation or a statement made by the defendants is correct.

On Page 10 of defendants' November 18th letter, they say, quote: "And there were simply no testing procedures that could quantify or detect nitrosamine impurities at such trace amounts until the FDA introduced new testing procedures in June 2018."

We're not going to -- we can't decide today whether that's true or not. I just want to know if plaintiffs agree with that statement.

MR. SLATER: No.

THE COURT: Okay. And then I understand what the prevailing theory is about how this contamination occurred. Later on in the same paragraph that I referred to, the defendants say: "The purported nitrosamine impurity was introduced during the API manufacturing process."

What are plaintiffs' thoughts about that?

MR. SLATER: Oh, we believe that the nitrosamine

contamination occurred during the API manufacturing process. That's what we believe from what we've seen. Whether or not there also could have been contamination in the finished dose or downstream facility, we don't have enough information to prove that, but it's something we obviously have to look at, because there's obviously going to be cross-claims among the defendants and we have to see how they're going to handle that as between one another.

THE COURT: Will you be pursuing in the case, whether or not ultimately you pursue this theory, but at least in discovery, are you going to explore that there might have been some contamination introduced into the Valsartan during the finished dose manufacturing process?

MR. SLATER: We're certainly taking discovery on that and investigating it thoroughly. If it were to turn out that we have evidence that establishes that, then that would be an additional basis for liability as to the finished dose manufacturing.

THE COURT: Are you able to rule that out now?

MR. SLATER: We're not.

THE COURT: Is that one of the reasons why you want to conduct fulsome discovery directed to the finished dose manufacturers?

MR. SLATER: It's a reason, but it's probably a much smaller reason than the reason that the finished dose

manufacturers have regulatory obligations and had to test, to audit the API facilities and to be essentially fully conversant with everything that had happened.

For example, take Teva that bought the API from ZHP. Teva had a regulatory obligation to audit what had happened in China during the manufacturing process, to look at the test results, to look at the chromatography, to look at whatever information -- there's a whole host of things they're supposed to look at to make sure that they could comply with their good manufacturing processes obligations.

So, you know, they had an independent obligation -- if the API manufacturers weren't involved in this case, the finished dose manufacturers would be fully responsible for everything that the API manufacturers did, because they had an independent obligation to audit and make sure that these were bioequivalent, that they met the regulations, that they could comply with all of the generic drug regulations and that they were safe to be sold, to be ingested by humans in the United States of America.

THE COURT: Did this, in your view, maybe disagreement on this, did this obligation arise under the DSCSA, or some other regulatory or statutory authority?

MR. SLATER: I think that's part of it.

MS. HILTON: Your Honor, if I may, surely we cite to the drug supply security control act, but they have these

obligations under the basic Food & Drug Administration regulations and because they are the ANDA holders who submit their Abbreviated New Drug Applications to the FDA, the API is not obligated to test, but the ANDA holders indeed are.

So their obligations actually arise from their Abbreviated New Drug Applications.

MR. HONIK: And at the risk of being old-fashioned, Judge, the common law imposes a duty as well. I mean, if Boeing puts an airplane out and there's a defective engine that's a component part that it got from another party, which would be roughly equivalent to an API, and puts it into its plane, it can't raise its hands and say we had no obligation surrounding that.

So in addition to the regulatory scheme, which is as tight and formative as one could find in any regulated industry, certainly the common law imposes a duty on the seller, the finished dose manufacturer, who is incorporating this component part, that may very well be the rub of this case.

THE COURT: Let me ask one more question of the plaintiffs and I definitely want to hear from the defendants on this. I'm not quite sure how to phrase this question, but I think it's important because so much of the theme running through defendants' papers is, we should defer to the FDA's thinking and prevailing theories and if this is what the FDA

thinks, why, Judge, are you letting plaintiffs go off on these alternative theories.

How much stock are plaintiffs going to put in the FDA's findings and prevailing theories?

MR. SLATER: The plaintiffs are going to consider what the FDA found, we're going to consider the information that they have accumulated through this process and ultimately, though, we are not going to rely on the FDA's conclusions for multiple reasons, including the fact that the FDA, we think, has a part to play in this, because they missed this, they failed to follow through on some warning letters and to take some steps against at least ZHP, that probably should have been taken and we think that the FDA probably has some incentives to play down the ultimate significance of this issue. I mean, we could talk about that more another time.

So we're going to use the evidence that we're getting through the FDA. We think a lot of it is very damaging to the defendants, obviously, because this caused -- I think it's the largest Class 1 recall ever. So obviously, the FDA wasn't happy about what happened here and determined these drugs could not be sold in that form, so we think they've done a lot to prove our case, but we're going to go well beyond that and we're going to have to establish in a more granular way the elements of our case here.

MR. HONIK: There's another piece to this as well, if

I may, Your Honor. This is an ongoing investigation which, frankly, has a political component. And what I mean by that is, that the defendants, through their counsel, have engaged and continue to engage with the FDA in a very active way. We're not a part of that, consumers are not a part of that, buyers are not a part of that.

THE COURT: How do you know that?

MR. HONIK: Well, because it's in the public domain and because, as we get FOIA information, we see the contact between counsel.

THE COURT: Shouldn't you be getting -- apart from FOIA, didn't the Court order that contemporaneous communications have to be produced?

MR. SLATER: Yeah, it's a big problem because we don't know -- we don't think they're being updated and the --

THE COURT: I court-ordered that twice.

MR. SLATER: Yes, and Duane Morris, for example, is the liaison to the FDA on what's -- on this investigation that's ongoing. So Duane Morris is in, as Mr. Honik just said, in direct communication with the FDA on this issue. So, yeah, and we don't believe that we have updated communications. We think there's probably some significant gaps, but again, you know, we're not able to say, we don't have something, we just don't think we have a lot of what's been exchanged and continues to be.

THE COURT: One more question.

And I don't know how to put it delicately, but to put it bluntly, will the plaintiffs be questioning FDA's findings because they have issues with their potential biases and motivations in connection with this recall and investigation?

MR. SLATER: I would think that there's probably some conclusions by the FDA that we're going to differ in our conclusions and our experts will differ, and there may be some areas that we're going to want to go much deeper into than the FDA did, because we think there might be some answers there that they may not want or need, for what they're doing.

THE COURT: So, Mr. Goldberg, if you have anything to say, I don't want to cut you off, I'd like to hear from you on this. You may not have anything to say, but in light of plaintiffs' theory of the case, obviously you may disagree with it, you're entitled to do that. But plaintiffs -- I'm sorry, defendants argue again on Page 10 of the same letter, that finished dose testing and anything downstream is simply irrelevant. That's the defendants' argument.

How can you take that position in light of plaintiffs' theories of the case?

MR. GOLDBERG: Your Honor, if I can just sort of back up and then come to that question.

THE COURT: Absolutely.

MR. GOLDBERG: Okay. Can I approach, Your Honor,

with a couple of documents, please?

THE COURT: Sure.

MR. GOLDBERG: Your Honor, I think one of the ways you started this conversation was about the manufacturing process and whether plaintiffs agree that this is about a specific part of the manufacturing process.

THE COURT: No, what they said was -- if I'm wrong, they will clarify it, but I think -- my takeaway from what the plaintiffs said is, yes, they seem to agree with the prevailing theory that this contamination occurred during the manufacturing process, but they're not ruling out at this time that there also may have been contamination caused during the finished dose manufacturing process.

That's how I understood -- they're not saying exclusively the manufacturing process. That's how I understood what they were saying.

MR. GOLDBERG: I agree with you, that is their theory that they can't rule out that there was some other contamination.

Your Honor, I've handed you what is the current manufacturing process for ZHP's Valsartan, and I just think it would be helpful, we haven't really talked about the science too much and I'm not an expert in the science and there's going to be experts here, but, Your Honor, what I've given you is the multistep process to make Valsartan.

THE COURT: You know, this is exactly why I was a political science major.

MR. GOLDBERG: Me too, me too.

(Laughter.)

MR. GOLDBERG: But, Your Honor, I just want to show you, if you turn to the bottom, to Prinston 612, bottom left, this is Page 7 of 21, this is Step 4 of the multistep process, and what this -- what I understand from the documents that I've reviewed, from the different briefs in the case, including Page 4 of plaintiffs' brief, where they're talking about a specific moment where solvents are introduced to the -- to the manufacturing process, that happens right here, Step 4, where you see it says tetrazole reaction at the top, it says quenching, and if you look to the left, you'll see where it says DMF solution in a box.

THE COURT: Yes.

MR. GOLDBERG: Okay. This is -- DMF is the solvent that's being introduced. This is what's been talked about. This is the moment, this is the chemical reaction. If there is one, this is the moment that they're referring to. This is what this case appears to be about at this point.

Don't -- we don't know exactly what happens, you'll hear from experts about what happens, but this is really important to sort of isolate this moment in time, because you can see all of the steps that happen before, all of the steps

that happen after. This is in the moment of creating the powder at the API facility. This is not the moment of making a pill at the finished dose facility, putting it in a bottle, selling it.

Plaintiffs may say to you they can't rule it out, but the logical conclusion is that the contaminations that are caused -- allegedly caused by DMF, that they've pled in their case are happening here where the DMF is introduced. That's the answer to the question. That's their theory. We don't see how it translates to the finished dose manufacturing process. No evidence that DMF or any other contaminant is being put into the drug at that point in time. This is the process.

I wanted to just address the testing question, the question about whether testing was around at the time to detect NDMA. I've handed you the FDA's press release, Your Honor.

The second page of the FDA's press release, this is August -- January 25th, 2019. This says -- Page 4 of 6, which is in the very bottom, bottom left of the page. During this time -- this is in the time since the recall, so we're in January of 2019, we're talking about the last six months. During this time, our scientists have developed and refined novel and sophisticated testing methods, specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines.

And then it goes on to describe the three or four tests. At the time that the recall happened, I don't think we're saying that there was no ability to identify NDMA. Chromatography existed. Gas chromatography, liquid chromatography existed. I think the point is that nobody had their machines at the sensitivity, nor did the FDA, to detect NDMA and NDEA at the trace amounts that were found.

Did a customer have their machine at the right sensitivity? Apparently. And so since that time, the FDA and all of the other manufacturers have been spending their effort in this investigation to refine the testing, to get it to be sensitive enough to identify the trace amounts of NDMA and NDEA in the drug, and that's -- that's the point of what we said in Page 10. Maybe it wasn't as specific as it should have been, but that's what we intended by the fact that -- and that -- and that was the state of the art at the time.

MR. REEFER: Excuse me, Your Honor, may I just make one statement? Judge, I know that --

THE COURT: I'm sorry.

MR. REEFER: I'm sorry, Jason Reefer for Mylan Pharmaceuticals.

I know that the issue of foreign evidence is going to come up today, and so with the magic of Google, I tried to look at some of the foreign regulatory documents that might be out there, and, you know, this is a statement from the

European Medicines Agency, EMA, which in my mind is sort of like the European FDA, that might not be precisely correct, but this is a line from an April 17th, 2019, statement that they made with respect to the nitrosamine impurities and the recalls.

THE COURT: What's the date again, sir?

MR. REEFER: Sure. April 17, 2019.

It says: "Before June 2018, NDMA and NDEA were not among the impurities identified in sartan medicines and were therefore not detected by routine tests." That's the EMA.

THE COURT: I don't think that really helps advance the ball, except to clarify what the Court has to rely on when it decides the scope of discovery; one, plaintiffs' claims and your defenses in the case; and two, that's exactly why I asked Mr. Slater one of the questions, are they deferring to the FDA and the EMA, and they're clearly not, because they question their biases and motivations.

So the Court has to take that into consideration when it rules on the scope of discovery. It can't take as gospel the FDA's statement that this may have been the state of the art, or what this test was or was not available, because plaintiffs are challenging those assertions.

MR. REEFER: But I don't know that they're necessarily challenging the assertion that routine testing would have picked up these impurities at the levels we're

seeing.

THE COURT: But I don't want to take the wind out of plaintiffs' sails, but it's no surprise that their -- plaintiffs are going to argue that the routine testing was wrong, that the defendants knew or should have known that the routine testing was inadequate. I don't think -- it's no surprise you're making that argument, plaintiffs, right?

MR. SLATER: Not only that, but that the routine testing, if it was actually evaluated appropriately, would have led any reasonable person in the defendants' position to say, we need more information. We're seeing artifacts and impurities and, quote unquote, their terminology, ghost peaks on chromatography, that we don't understand why we're seeing these things, and instead of doing what they did which is saying, oh, it's just an artifact, we don't have to worry about and moving on and plowing over it, that they should have taken a step back because they sit here and say, well, there wasn't a test to specifically identify a nitrosamine because they didn't know to look for a nitrosamine, but they certainly knew to look on the chromatography for the purity and to see if there were peaks and findings that didn't correlate to what they expected to see, which under the law, under the regulatory responsibilities, triggered their obligation to do more, and they -- and if they had done that, they would have found out, oh, these are nitrosamines, if they did what they

should have done, because again, they sit here and say, nobody could have found it out, but somebody did find it out, a downstream purchaser did test it, did find it, did go to ZHP and say, hey, we're not taking this, you have a problem here and that's how this entire thing came out.

So every time they stand up and say, well, the FDA says no one could have figured it out, it's absurd, because somebody else actually did and that's why we know about it.

MR. GOLDBERG: Your Honor, I --

MR. SLATER: Oh, and the other thing I'll say is this, just -- I'm sorry, Mr. Goldberg.

I thank Mr. Reefer for making a good part of our argument on foreign regulatory and acknowledging the relevance of foreign regulatory findings and documents by referring to the EMA because that is one of the reasons why that it's relevant, because they've been looking at this question, too, and there may be communications with those regulatory authorities different from those with the FDA. That's why we need all of them.

MR. GOLDBERG: Your Honor, I kind of was talk -- the documents that I've shown you, I don't, I don't think there's a disagreement about what plaintiffs' theory is, and you're right, that statement doesn't necessarily advance the ball as to their theory, should have known, should we have identified in the test. But what Mr. Slater just did was exactly what we

have been trying to do, which is to demonstrate to Your Honor the narrow issue in the case, which is chromatography testing about these nitrosamines, about impurities and residual solvents.

That's the theme in our briefing. That's what this case really is about, and it's really up to the parties and the Court to figure out, can we stay focused on that issue or are we going to expand this to something that has, you know, far more to do with general manufacturing practices, far more to do with slinging mud about Chinese and Indian companies, far more to do about different aspects of a manufacturing process that have no bearing on that moment in time, that moment in the process where the chemical reaction happens, the moment that's being investigated by all of these agencies.

And if we can't stay focused on that, we're going to be in a quagmire. We'll be here for years, looking at hundreds of thousands of millions of pages of documents that have nothing to do with the chemical reaction that happens at the moment when DMF is introduced in Step 4 of the process.

That's the task at hand here. And to get side -- you know, go sideways and get sidetracked with so many other things is -- is going to result in, A, a morass and, B, exactly what discovery is not intended to do, which is to somehow raise costs and expense so high that it forces a settlement.

THE COURT: Okay. I would say in response to one of the comments you made that testing is -- we're going to deal with it today, it's certainly a very big issue. I would be delighted if plaintiffs stand up and say, we agree that the only relevant test to detect nitrosamines is these chrome -- whatever they are.

MR. GOLDBERG: Sure.

THE COURT: If they agree to that, I would be delighted, but -- but my instinct tells me that's not going to happen.

MR. GOLDBERG: And I don't expect them to.

THE COURT: And I don't think -- clearly, they're not going to get tests, have to do with color and taste and shape and size. Those issues aren't relevant to the case. They're not going to get those tests. But suppose they say, you know, Judge, this type of test could lead someone to identify whether there's a contaminant of concern in the API or finished dose.

MR. GOLDBERG: If they come up with that kind of test and present it to Your Honor, it's a great thing for us to talk about at that point in time.

THE COURT: Okay.

MR. GOLDBERG: Simply, the theory that some other test may indicate, without identifying what kind of test that is, and I think we actually aren't that far apart on testing

after hearing their -- reading their brief. I mean, it seems like the parties are in general agreement about chromatography testing and bioequivalence, and that does seem to be where we would want be on testing, and it doesn't seem like there's a whole lot of dispute there.

Now, later in the case, should there be this issue, how could we say no at that point? But we -- that hasn't been presented in that way to the Court yet.

THE COURT: Okay. We'll get to testing in a few moments.

Another question for the plaintiffs, and it relates to the one issue I really don't have my arms around yet, and that's the relevant time for discovery for each of the defendants. Everything else I think is going to fall into place and I need your help on it.

Plaintiffs -- I'm sorry, defendants. The Court's understanding is defendants' argument is that only -- the only Valsartan at issue in this case is the Valsartan that was recalled. That's defendants' theory. And the follow up to that is, so since only the recalled Valsartan is at issue, only the facilities that made the recalled Valsartan are at issue in the case.

What's plaintiffs' thinking on that issue?

MR. SLATER: Well, there's a lot of contaminated Valsartan that people took from lots and batches that were

used up before the recalls occurred, No. 1.

THE COURT: How do we know that? Why is that the case?

MR. SLATER: Even if we take, for argument's sake, Mr. Goldberg's theory or ZHP's theory that this started when they made their change in their process and started to sell this drug into the U.S., they were selling it to the U.S. for several years before one of their customers brought to light that this was a contamination problem with nitrosamine.

THE COURT: The change in process was when?

MR. SLATER: 2011. Correct?

MR. GOLDBERG: December 2013 is when the change was finalized and approved, Your Honor.

MR. SLATER: Oh, you're right. In 2013, they put it into place.

So -- but they were selling into the U.S. for a long time before this came to light, so there were drugs that were taken that were -- and those lots and batches, there's no reason to recall it because it's already been used, and if they're right, that this is when -- that this process created the contamination, then it was all contaminated.

THE COURT: So let me ask you this question. I'm sorry for interrupting, Mr. Slater, but if this manufacturing process, let's say, was put into place online in December '13, and the contamination wasn't discovered until July 2018, you

know, four or five years, plaintiffs' theory is -- is plaintiffs' theory that all Valsartan made during that time, using the same manufacturing process, was contaminated?

MR. SLATER: Yes, unless they can prove it wasn't, which is where I've been for months with the defense and with the Court to say, let's get together and define the entire field of all Valsartan that was sold in the U.S., let's identify that which the defendants' agree was contaminated, let's identify that which they say may have been contaminated, and let's identify that which they say wasn't, and then we can really take the defendants at their word and say, now we can focus a very important issue in the case, because you'll see, when we ask those questions in core discovery, we got a gauntlet of objections to -- trying to establish that.

But why wouldn't it be all contaminated? They've just told us, this is the part of their process that caused the contamination. If they use the same process for every pill, every pill was subject to the same contamination. That is -- I don't see how they argue against that and I don't know, maybe they can make a statement for the Court to try to narrow issues right now.

I would assume they agree, yes, every single Valsartan pill we sold into the United States, certainly ZHP will say, yes, it was all contaminated or likely contaminated.

MR. HONIK: Your Honor, let me, if I may, to shed

some light because you are asking a critical question about scope, right? What facilities, what products, and temporally, what are we talking about here.

THE COURT: Absolutely critical questions.

MR. HONIK: Let me direct your attention to -- this is a recipe, right? What Mr. Goldberg handed the Court is a recipe with many, many steps, and he says to the Court, the only step you need to worry about is on Page 7 of 21, Step 4, that's when we introduced the DMF solution. Now, we quarrel with that for the reasons you've already heard. But let me spin this out so you can understand and hopefully appreciate the scope and the temporality that we're talking about here.

If it's true that the DMF solution is the main culprit, maybe the sole culprit, then we have to ask ourselves, when were they starting to introduce this DMF into their process?

THE COURT: Fair question.

MR. HONIK: And the answer, Your Honor, is, it began in Process 1 in 2007, September. That's when they started to introduce this ingredient into the recipe in their pills.

We have already seen, albeit not a lot, but we have already seen peaks from testing that they've produced to us that goes back before the timeframe in question.

That's DMF in Process 1. They continued to use it in Process 2, which they submitted to the FDA for approval as

early as 2010. The manufacturing change in question was then subsequently proposed in November of 2011 and as Mr. Goldberg pointed out, finalized in 2013.

Sitting here today, even if we were to agree that the DMF and its use was somehow the culprit here, we can't say with absolute certainty without looking back, why did they choose it, why did they put it in their DMF application to the FDA? We have to see the thinking process behind their choice of Step 4 in this recipe, A, to validate whether, in fact, that's the immaculate conception, I mean, that's the theory they're coming up with, that you don't have to look at anything before or after, because it occurred at that split second.

We don't know that. As plaintiffs in court, we should be permitted to supply to our experts and allow them to verify whether the theory they're presenting is really true, if it holds water a little bit or a lot. But the fact that this step dates back to their own application to the FDA in 2007, implicates their choosing that DMF solution, implicates the process that they chose.

I think this best exemplifies how, at this point in the litigation, where we haven't really undertaken substantive discovery beyond the core discovery, that we need to go back and ask the questions.

It's fair to do so, and it's a mistake to think that

plaintiffs are simply creating tasks for the defendants to do. Whatever they produce, we have to look at, on our time, at our expense, and we're not interested in making work for ourselves, but we are interested in understanding whether the recipe theory that Mr. Goldberg has proposed to us, actually holds water. That's what we want to look at.

THE COURT: Let me ask you a question, and I remember asking these questions at -- if not the first conference, one of the first conferences. We know that the FDA recalled X number of lots. Presumably, the reason they recalled those lots, presumably, I don't know, is because those lots were tested or a sample of those lots were tested and they were positive for contamination.

Are those all the lots that were made during that time?

MR. SLATER: No.

THE COURT: Were there tests done on lots that didn't detect contamination, and those specific lots were not recalled? Were some lots -- were some tests positive and some tests negative?

MR. SLATER: I think you have to go defendant by defendant.

THE COURT: Does anybody know that?

MR. SLATER: I think you have to go defendant by defendant and look at the test results, because there's

different findings per defendant, and that's again -- what we're trying to do is to establish what were all the tests done and I'm sure there's a lot of tests that we don't know about yet that weren't done as part of the recall, that may or may not have shown impurities that should have been disclosed, but all of the pills were not tested, for sure.

MR. NIGH: Your Honor, in terms of our understanding, the FDA directed the defendants to go back and test the pills that were unexpired at the time that the FDA was -- found out about this issue.

So we even heard Mylan, I believe, Clem months ago say and agree that that's what they did, they only tested the unexpired pills. We have reason to believe Mylan has been selling this since 2012 or 2013. They would have only been testing back to 2016 because that's when unexpired pills --

THE COURT: So hypothetically, I'm just making this up. Mylan has a hundred lots of unexpired pills.

MR. NIGH: Right.

THE COURT: I don't even know -- how many pills? No one ever told us how many pills are in a lot or how many bottles are in a lot.

MR. NIGH: Yes.

THE COURT: The recalled lots, was that all 100, or was it 25 of the 100 lots, and if so, does that mean that some tests were positive for contamination and some tests

weren't --

MR. NIGH: Right.

THE COURT: -- didn't detect contamination? Do we know the answer to that?

MR. NIGH: We don't. We have an incomplete set of testing from my eyes, and from our risk assessment expert looking at it, says, we're missing a lot of pieces to what we would want for testing. It would be not only important to see the testing for what hits is a contamination for over 96 nanograms, but it would also be important to understand all the testing for the not detected nanograms in that same lot, and that's what we -- we don't have a full picture on the testing.

THE COURT: Do we know how the FDA determined that certain lots were going to be recalled and certain lots were not going to be recalled, and the identity of the not recalled lots, and hypothetically, because I don't know, suppose there's a hundred lots, 25 were recalled, what does that do to the theory that every pill or all API made during that time period was contaminated, if there were 75 of a hundred lots that were not recalled?

MR. NIGH: Yeah, and I think this is a defendant by defendant issue. ZHP, my understanding, they've come out, they've expressed that every Valsartan pill that made its way into the U.S. was over -- was heavily contaminated over the 96

nanograms. The other defendants would have been -- the direction, my understanding is the FDA looked to the other defendants and said, test your unexpired pills for each lot, come up with a protocol as to -- but if it's over 96 nanograms, we need to issue a recall of that lot.

So we were still going to have contamination even under 96 nanograms for unrecalled lots in the unexpired.

THE COURT: Do you have all the test results -- once the contamination was discovered, and the FDA directed that testing be done in order to identify what had to be recalled or not, do you have all of those test results?

MR. NIGH: No, no. I mean, one example would be -- I'm certain we don't have all the testing results for Teva. You know, Teva is -- they have the combination that has a lower level of contamination and they have just Valsartan that clearly has their higher level of contamination. We don't have that testing for the higher level. So that's just one example.

THE COURT: Is there anything you want to add on this, Mr. Goldberg?

MR. GOLDBERG: I guess a couple of points to clarify. One thing to clarify with respect to ZHP, and going back as Mr. Honik was saying. The only ZHP pills that have been sold in the U.S., APIs sold into the U.S., only happened after 2015, when we -- when ANDA filers using our API were approved.

So we were manufacturing product prior to 2013 using a different process, and if Mr. Honik is correct that DMF was used during that process, so be it.

Drugs made from that process were not sold into the U.S., which is why in our briefing, we tried to draw a line with respect to the relevant time period as it relates to ZHP and I think probably as to some of the other defendants.

THE COURT: Do I take it then ZHP was selling API around the world before 2015 but only as to the United States after 2015?

MR. GOLDBERG: I believe that's correct. I'm not sure which countries around the world. I know in China they were, but I'm not sure which, but for U.S. sales of ZHP API, it only occurred after 2015 -- since 2015, and we provided that information to plaintiffs, our letters of authorization are in the document.

So our thinking on relevant time period is, and it does go back to this. I don't know that it's a recipe, and I'm not suggesting that this one moment in time is the only relevant part of the process, but what I am suggesting is that this is -- you know, this is the most important part that should really guide how we look at discovery.

The -- sorry, I lost my train of thought, about the -- oh, I think what I would -- what we are suggesting about this process, with respect to relevant time period is, to the

extent there are specific questions about the process that predate 2015, then let's focus on those, but certainly general discovery as to all of these other topics in the 122-some-odd requests don't need to go back that far, and that a cut is 2015, and then, you know, if there are specific questions, specific questions about residual solvents, impurities, this step in the process, some other key step, then raise it that way, and so that we're not mired down in a morass of documents that date back into, not only more than a dozen years as to some defendants, but also with respect to processes and pills that are not at issue in the U.S.

MR. NIGH: Your Honor, if I can clarify a few things. For ZHP, they have three different processes as to how they make their Valsartan from what we understand. They've got a TEN process, it's called Process 1. They have a TEA process called Process 2, and then a DMF Process 2. Those are the three different types of processes. So the recipe that was shown is DMF Process 2.

The problem with what we just -- and the Chinese -- ZHP alerted the FDA, they said, this is the reason for their problem, it's Process 2 DMF, and we're hearing it again that we should limit it to just DMF Process 2. That's the issue.

But the problem is, we've submitted a Claussen report, 58-page inspection report from Claussen in 2018. She asked Jun Du and asked, well, did you test, did you get

testing results on the other processes, and they again said, there's no problem with the other processes, but the FDA said, but did you test them.

Well, guess what happens? The day before the inspection concludes, they come back and they reveal, there are very high levels for TEA Process 2, so now it's not just Process 2 DMF, it's also Process 2 TEA, that we don't know even utilizes DMF. So I don't think that we can just define this and say, that's the only problem that we know about, and also to say that Process 2 DMF is the only one that makes its way to the United States.

I don't believe that's accurate, but I'm not certain, but I don't believe that's accurate. I believe it's being sold to Torrent and it makes its way into the United States.

So that's another reason why we need to find this out. We would then need to understand, if all that's accurate, we would need to understand why is it, if Process 1 doesn't have a high impurity finding, but Process 2 TEA does and Process 2 DMF does, that could be our answer. That's why we would need discovery into all three of the processes for ZHP.

THE COURT: Okay. Real quickly, couple of questions.

Are you going to orally argue the motion in December before the JPML panel?

MR. NIGH: I am not, because they are not asking for

oral argument.

THE COURT: Okay. Am I correct that Hetero Aurobindo India, they haven't been served yet? Is their counsel here for the U.S. entity?

MS. POLETO: I am here, Your Honor.

MS. HEINZ: Yes, Your Honor.

THE COURT: They know -- you don't have to answer this. The train has left the station. When they eventually come into this case, they're going to have a lot of catching up to do quickly, because they're on notice of everything that's been going on in the case, so they had the opportunity -- they're exercising their right, perfectly appropriate, no problem with it.

But if they think they're going to come into this case and we're going to start at ground zero, they're mistaken. That's the only thing I wanted to say. You don't have to respond, but I just want to make sure they know that the train has left the station. Okay?

MS. POLETTO: Duly noted, Your Honor.

MS. HILTON: And, Your Honor, if I may, Hetero Drugs did receive a Complaint in India. Counsel for Hetero USA forwarded it to me. It was one of the Longwell class Complaint and was filed in the District Massachusetts -- Hetero Drugs in India received a copy of our Complaint, we received a copy of it from counsel for Hetero USA and it

included the Indian certificate on the front and it was -- it was one of our Massachusetts class complaints, and so they are in receipt of the Complaint, but we just have not received -- I personally have not received a signed certificate back from India which takes, you know, a month or two months.

THE COURT: Once the two companies are properly served pursuant to the Hague or at least you get evidence of that, do you know how long they have to respond to the -- well, no answers have been filed, so I guess what I'm asking is, how long after they're served, do they enter an appearance?

Or let me put it this way. As soon as -- will you be the person who gets notice that the two companies have been properly served pursuant to the Hague?

MS. HILTON: I believe I'll get some sort of documentation from India. I don't know what that looks like.

THE COURT: All right. The Court wants to know immediately, because we will order that an entry of appearance be entered, and if we have to, we'll enter an order saying those specific parties have to file answers to the Complaint, and if they don't, there's going to be a default, because I don't want any undue delay after they're served while they wait and finally get around to entering an appearance.

I want them in the case as soon as they're properly served. So let us know when that happens. Okay?

We're not going to grant undue extensions of time to enter an appearance or file this or file that, clerk's order, blah, blah, blah. Those days are over. Okay?

One more question and then we'll get to the specific issues that we have to deal with.

Teva's counsel.

MR. RUBENSTEIN: Yes, Your Honor.

THE COURT: I'm not quite understanding this Malta facility issue. If it's just a question of whether they fit into the category of facility that has to respond to discovery, that's fine, we'll deal with this, but do we have a successor liability issue that has to be addressed in the first instance before we get to that?

MR. RUBENSTEIN: No, I don't know, there is no issue. Teva is not going to be withholding documents from Malta. Malta was one of the manufacturing facilities that made Valsartan for sale in the United States.

Teva will be producing documents regarding the manufacture, you know, the process and everything, the testing that was done there. Teva will be producing those documents, so there is no that I, you know, issue with the Malta facility.

THE COURT: Okay. So there will be --

MR. RUBENSTEIN: It doesn't exist anymore as a legal entity.

THE COURT: We don't have to deal with the successor liability.

MR. RUBENSTEIN: No.

THE COURT: Okay. Let's -- now I'm ready to -- or the Court is ready to get to the specific issues in the dispute, and in looking at it, it made sense to me to start with the issues that plaintiffs started on, and then we'll go to defendants, and I suggest we just go down the order -- in the order.

The first issue is what the Court called boilerplate objections. The Court -- that's the only issue the Court doesn't need oral argument on.

I read the briefs, read the papers. I understand everything. I don't think you can add anything to the record.

So let's move on to issue No. 2. What entities or facilities must respond to plaintiffs' discovery. Pretty important issue.

Let me ask you this: Do we at least know how many facilities and what the facilities are that we're talking about?

MS. HILTON: Well, all of the facilities, if I may, Your Honor, all of the facilities that are used in the manufacture of finished pills that enter the U.S. market pursuant to --

THE COURT: Let's start with the API.

MS. HILTON: We know which facilities were used that manufacture, and you'll note that defendants were very clear in their language. Valsartan API, that was subject to recall. This leads me to believe that there are, perhaps, facilities they have not identified.

THE COURT: Well, that's the question. That's the question I asked. Do we know at least the universe of facilities that made API as a starting point and then we can identify the facilities that had recalled API, the facilities that sold U.S. API and the facilities that only sold foreign API. Do we know that?

MS. HILTON: No, Your Honor, we don't. We only know which facilities manufactured API that was subject to a recall. That is what defendants have given us. We know the universe of facilities that defendants have generally, but it is possible that some facility or some process may make API, and in another facility may make finished dose. They have just been very clear that they are only providing us with --

THE COURT: Let's just start with it -- first, we're going to start with API. That's different from finished dose. Are they separate facilities?

MS. HILTON: Based on my understanding, sometimes they are not.

THE COURT: Okay. So defendants say, we want to limit the facilities at issue to only those that sold the

recalled API. Do we know right now whether or not that's the universe of all API facilities?

MS. HILTON: We don't know that, and we have reason to believe that it's not the universe of all API facilities.

THE COURT: So what facilities do you think should be at issue in the case?

MS. HILTON: We believe any facility that manufactured Valsartan API should be subject to discovery.

THE COURT: Suppose I don't know, we don't know -- I wish we had the answers to these questions. Suppose there's an API facility that only made APIs sold to Belgium and France, obviously I'm making this up, they didn't sell any API that entered into the United States. Is it your position that discovery as to that facility is relevant?

MS. HILTON: Yes, Your Honor.

THE COURT: Why?

MS. HILTON: We understand that the defendants utilized different manufacturing processes, recipes as it were, for different countries, based on different guidelines and requirements those countries had.

So to the extent Belgium had no adulterated contaminated Valsartan with nitrosamines, we would be interested in seeing what those testing results look like, what those documents look like and whether, you know, because another Valsartan was showing aberrant peaks, the defendants

should have been on notice. If there was a country that had an adulteration or contamination that was at even higher levels than the United States, you know, we would want to see that testing so we could compare.

THE COURT: Mr. Goldberg, isn't it just a basic, basic, basic fact to identify the universe of potential facilities at issue?

MR. GOLDBERG: Yeah, I'm not sure -- I'm not sure they haven't been, Your Honor.

THE COURT: Okay, so --

MR. GOLDBERG: I know for ZHP, plaintiffs know where the stuff is made.

THE COURT: Okay. Just as -- I'll ask the other party, just ZHP. ZHP wants -- as well as the other API people, want to limit the facilities at issue to only the facilities that made the recalled API, right?

MR. GOLDBERG: Well, for us, that's our Valsartan.

THE COURT: So as to --

MR. GOLDBERG: We voluntarily recalled everything that came to the U.S.

THE COURT: So it's all of your API manufacturing facilities?

MR. SLATER: We have Chuannan and we have Xunqiao. And Chuannan is where the API is made. Xunqiao -- Chuannan has two -- we have two zones and Xunqiao, I believe, is where

the finished dose is made, and we have said they can have discovery as to both.

THE COURT: Okay. So it's easy with regard to your client.

MR. GOLDBERG: Correct.

THE COURT: Mylan?

MR. REEFER: Hi, Judge. Yeah, Mylan has identified all of the facilities that have manufactured Valsartan API, they're referred to as Unit 8 and Unit 3 and we've provided their identification information.

THE COURT: Did they both sell recalled API?

MR. REEFER: I believe so, Judge.

THE COURT: So we don't have an issue -- well, are those the only two facilities that made API for your client?

MR. REEFER: Valsartan API, yes, Judge.

THE COURT: So we don't -- so far we don't have an issue with ZHP, we don't have an issue with Mylan.

MS. HILTON: Your Honor, if I may. I mean, could we get confirmation that they're not limiting it to just the United States and that they are answering with respect to all of their processes around the world, because --

THE COURT: They just said that they only have -- you have two facilities, you have three facilities, right?

Do you have any -- all right.

Mylan, do you have any API manufacturing facilities

that exclusively sells to non U.S. customers?

MR. REEFER: No, Judge.

THE COURT: ZHP?

MR. GOLDBERG: No, Your Honor.

THE COURT: So right now, Mylan and ZHP are the only API manufacturers in the case, right? Because Hetero and Aurobindo are not in the case yet, right? Okay.

MR. GOLDBERG: I believe that's correct.

THE COURT: So we don't really have -- well, that's API. Let's go to finished dose.

MS. HILTON: Yes, Your Honor. So the defendants -- first of all, I think Mr. Rubenstein said earlier that they did not produce establishment inspection reports in core discovery. That's actually not correct. The finished dose manufacturers did. I looked at some last night. So I know that some of the finished dose facilities, Aurolife, for example, did produce establishment inspection reports.

And so we know, we believe that we are entitled to discover especially quality assurance-related documents.

THE COURT: No, no, no, let's not move on to the next issue. We're just talking first --

MS. HILTON: Oh, identification.

THE COURT: Right. First, we're going to identify the facilities at issue, and then we'll get into the specific documents.

So I take it, you want the defendants to produce responsive discovery for all finished dose manufacturing facilities, not just those that sold recalled products?

MS. HILTON: Yes, Your Honor.

THE COURT: Okay. We don't have an issue with ZHP, Mr. Goldberg, as I understand it, right?

MR. GOLDBERG: Correct, to the extent we're going to produce finished dose manufacturing-related documents, they're at Xunqiao and that's the one.

THE COURT: Right. So Mylan, do you have finished -- separate finished dose manufacturing facilities?

MR. REEFER: Yes, Judge. Nashik in India.

THE COURT: Is this apart from the three API facilities?

MR. REEFER: To clarify, Judge, we have two API facilities, one's called Unit 3. It no longer manufactures Valsartan API as of, I believe, 2017. Presently, the only Valsartan API manufactured by Mylan is done at Unit 8 which again has also been identified.

Separately, we have finished dose facilities in Nashik, India, and Morgantown, West Virginia.

THE COURT: Did both of those facilities sell recalled finished dose products?

MR. REEFER: Yes, I believe so, Judge.

THE COURT: Okay. So we don't have an issue with

Mylan.

MS. HILTON: So we have several issues with Mylan but in terms of identification --

THE COURT: Of their facilities.

MS. HILTON: -- of their facilities.

THE COURT: One step at a time.

MS. HILTON: Yes, Your Honor.

THE COURT: Teva, your finished dose manufacturing facilities are located where?

MR. RUBENSTEIN: In Jerusalem and Malta.

THE COURT: Did both of those sell -- well, I'm not sure about Malta. Did both of those sell recalled Valsartan?

MR. RUBENSTEIN: Yes. They're the only two facilities that manufactured Valsartan for sale in the United States, whether they were recalled or not.

THE COURT: Is there a -- I know we're going to get into specifically what documents, each of facilities has to produce, but is there a dispute that documents are going to be produced from both of those facilities?

MR. RUBENSTEIN: No.

THE COURT: Torrent. Your finished dose manufacturing facility is located in India?

MS. NAGLE, correct.

THE COURT: Is there only one?

MS. NAGLE: Yes.

THE COURT: Did they sell recalled product?

MS. NAGLE: Yes.

THE COURT: Okay. So we don't -- we don't have any dispute anymore because all API -- API manufacturing facilities and all finished dose manufacturing facilities of the defendants sold recalled product, so we don't have an issue so far.

MR. SLATER: Your Honor, I may have missed it. But on Teva, what we were told is those were the facilities that sold to the U.S., I think we just lost the one piece. Did they have facilities that manufactured Valsartan for sale in other countries solely and not in the U.S.?

MR. RUBENSTEIN: Yes, they have other facilities.

MR. SLATER: So we're looking for discovery from those facilities as well. So we need to make sure we have those. I don't know that we do.

THE COURT: Okay. That was -- I'm sorry, Teva.

MR. RUBENSTEIN: Correct.

THE COURT: The two facilities that sold recalled product, they're located where?

MR. RUBENSTEIN: In Jerusalem and formerly in Malta.

THE COURT: And the finished dose facilities that sold only to non-U.S. customers, that's located where?

MR. RUBENSTEIN: There are multiple. I don't know off the top of my head.

THE COURT: Okay. So plaintiffs' position is all of the facilities, whether or not they sold recalled product, have to be subject to discovery.

Defendants' position is, it's only -- really only pertaining to your client, that the facilities that didn't sell recalled product should not be subject to discovery.

MR. RUBENSTEIN: That didn't -- that didn't manufacture product for sale in the United States. Whether it was recalled or not.

So if a facility that may have manufactured Valsartan solely for sale outside the United States should not be subject to discovery, but the two facilities, Jerusalem formerly Malta manufactured Valsartan that was for sale, they're the only two facilities that manufactured Valsartan, finished dose products for sale in the United States.

THE COURT: Okay. The issue is joined. I understand the issue, I understand the arguments. Yes, Mr. Slater.

MR. SLATER: There's just one thing Your Honor needs to be aware of. It may be that a Teva facility may have sold solely to a non-U.S. market, but that someone in that non-U.S. market may have then repackaged and sold it into the U.S., so --

MR. RUBENSTEIN: That's not my understanding.

MR. SLATER: We just want to make sure we don't miss something because our understanding was some foreign entities

may have purchased the drug from -- higher in the stream of supply, and then directed it into the U.S. We just want to make sure we don't miss something like that.

THE COURT: Are most, for the finished dose manufacturers, is the stream of commerce, if they're going to sell the finished dose pill, would it go directly to the United States or would it go through somebody else to the United States?

MR. RUBENSTEIN: My understanding is that it goes through the -- directly through the United States.

THE COURT: Is that the same for Mylan and ZHP?

MR. REEFER: Your Honor, with respect to Morgantown, it is in the United States so --

THE COURT: That's easy.

MR. REEFER: That's the easy one. With respect to the Nashik facility, my understanding is it is distributed through Mylan Pharmaceuticals, Inc., which is a West Virginia entity that operates the Morgantown plant as well.

THE COURT: Correct.

MR. REEFER: So does that -- I think that's answering the question.

MR. GOLDBERG: And for ZHP, Your Honor, the finished dose that we make in China comes straight from our distributor in the U.S.

THE COURT: Okay. All right. That issue is joined

and we'll address that probably right after lunch.

Third issue, whether defendants should be required to identify and produce discovery regarding other products using the same manufacturing processes, solvents and/or testing as those for Valsartan API, plaintiffs in effect are requesting to open up discovery as to -- I take it all sartans and all processes that use, what, DMF?

MR. SLATER: I don't think limited to the DMF process, because there's a prior process as well.

THE COURT: Okay. That's a pretty big expansion, plaintiffs. Why do we need that?

MR. STANOCH: Hi, Your Honor. David Stanoch for plaintiff. Judge, we know that certain sartans have the same chemical structure, right, that's the same Step 4 -- step we've seen on the ingredient list, that same thing is happening with the other sartans. We know that they're manufactured the same or substantially similar way, using the same or similar solvents, and that the testing results for the carcinogenic -- the impurities that we know from the recalls that's been found, at least some of these other drugs.

For the same reasons we were talking about earlier, if we're -- if we're detecting NDMA in losartan, that's a flag, that's a signal, that's a notice that it may be occurring in the same process, using the same solvents for the same chemical step for Valsartan.

THE COURT: Is there any evidence, any evidence, that any contamination was discovered in any sartan before July '18?

MR. STANOCH: I'm not personally aware of that, Judge.

THE COURT: I mean, plaintiffs are arguing they should have been aware of it, I know that.

MR. STANOCH: Correction, Judge, there were, of course, ghost peaks and other types of signals which we believe, at least from the limited discovery we have gotten so far, which should suggest that, that there was something there or at least further investigation should have happened.

THE COURT: So if you get discovery with regard to Valsartan, why then do you need all these other sartans?

MR. STANOCH: Well, again, again, Judge, we're not -- we don't want full discovery of every single thing about losartan, we're not saying losartan for example, is a search term, we're saying to the extent the manufacturing process in solvents were being used, which ones are being used for both processes, and if they were different and yielding different results, that's going to go to the knowledge and notice of the defendants.

THE COURT: So hypothetically, if you had a wish list of what you could find, what would you hope exists that you're not going to get through the Valsartan discovery?

MR. STANOCH: Well, it could be, hypothetically, you know, one of two things. Let's say, you know, we know for example, at some point ZHP was using a recycled solvent which some have suggested, one of multiple hypotheses, that the solvent itself might be the source of the contamination.

For example, we submitted with our briefing a 2019 statement about Lantech that was supplying the solvent where it was said that the solvent was what contained the NDMA. If they're doing the same process, with a different solvent for losartan and they're not finding that problem, then we know there's probably the problem on the Valsartan side. If they're using different solvents, right?

THE COURT: Last question. When -- again, not to take the wind out of his hand -- out of his sails, but I expect to hear from the defendants that these other products are not at issue in the case, these other processes are not at issue in the case. You're going to get, plaintiffs are going to get extensive Valsartan discovery.

The discovery that plaintiffs are requesting as to this issue is disproportional to its importance in the case. It's cumulative, duplicative, what have you.

How do you respond to that?

MR. STANOCH: I'd say that the defendants have not made a particularized showing of what that burden may be at this stage, Your Honor.

They're probably using the same or similar testing, using the same or similar machines, kept in the same or similar database, with the same or similar results.

We have had no showing that it's going to be some humongous process to go to a different facility with different custodians, different chromatogram machines, and different data extraction. It's all probably going to be on the same thing because they're all going to be coming off the same facility line using the same chromatography machine, going into the same computer.

They can just hit -- I know it's a simplification. I've been on that side myself, but the point is, it's going to be all in one place. And if you're queuing the data and you have to say Code 1 Valsartan, it's not burdensome to say also Codes 2 and 3, losartan, irbesartan.

THE COURT: Thank you. Mr. Goldberg, do you want to be heard?

MR. GOLDBERG: Thank you, Your Honor. I think Your Honor took the wind out of my sails.

THE COURT: Did I take the wind out of your sails? Excuse me for that, Mr. Goldberg.

MR. GOLDBERG: And obviously, this is an obvious significant expansion to this case. We do have the JPML motion and the JPML hasn't decided whether these drugs are even in this MDL. Obviously, discovery looks different as to

these drugs. If it does, until it does, the drugs, merely because they have a similar chemical composition, are not -- that doesn't make them relevant as to all of the same issues that are the subject of general discovery with respect to Valsartan.

Mr. Stanoch identified really what seems to be the issue which is not different than the issue for Valsartan. Chromatographic testing about impurities and with respect to solvents.

Now our view is, that information is going to be produced as to Valsartan. We've already produced batch testing for all of our Valsartan produced since 2013. We've already given them all of the batch testing records that would -- that's chromatographic testing as to NDMA, and the other defendants, I'm assuming are going to do the same thing.

At some point in time, if there's an issue that comes up that suggests, you know, we need to look at one of these other ARBs, with respect to a specific issue, maybe that very narrow discovery becomes pertinent at that point in time. But to open the door to four other drugs as to some general discovery, or even as to the chromatographic testing simply because they had a similar chemical structure, that is going to result in disproportion.

Now, I can't tell you, I think Mr. Stanoch is right, I can't tell you how many batch records that is, but we've

produced for just Valsartan and for defendants are produced with respect to ANDAs and DMFs, 200,000 pages.

So you're talking about ANDAs, DMFs, for all of these other drugs. If they want regulatory correspondence for all of these other drugs, if they want to get into custodial discovery as to these other drugs, they want to apply search terms as to these other drugs, they want to find out organizational charts as to these other drugs, they want sales as to these other drugs, whatever it is, we are going to, again, trying to keep the eye on the ball here, which is, you know, DMF or some residual solvent, impurities with respect to Valsartan. That's where the Court's going -- the parties are going to provide that discovery and this kind of an issue, if it's pertinent at all, should be revealed in specificity later in the process.

THE COURT: Okay. This here is joined -- oh, wait, we want to hear from some others.

MR. SLATER: Free fall.

THE COURT: Let's finish up the defendants, then we will give plaintiffs the last word.

MR. REEFER: Judge, I think I would be remiss if I stood idly by because I think that as has been alluded to several times over the process, there are defendant-specific issues. And so, for example, Mylan has recalled only Valsartan. Mylan has not had any issues with recalls of

losartan, irbesartan or any other sartans.

The solvent that's being referred to is DMF. Mylan does not use that solvent in its API manufacturing process.

So you see, Judge, I'm not sure what the Court is envisioning in terms of the issuance of an order, but I think that it would be outlandish to suggest that Mylan should be compelled to engage in discovery with respect to products that no one has alleged are defective.

THE COURT: So what's the working theory about what caused the contamination in Mylan's API?

MR. REEFER: Sure. You'll forgive me, Judge, I'm not a process chemist, but the short story is that Mylan has shown that this was a result of a recall -- I'm sorry, reuse of solvent with respect to a very, very specific sort of chemical pathway that occurs in the two steps of the API manufacturing process.

THE COURT: And when did that start?

MR. REEFER: That process was in place since -- I believe since Mylan entered the market, United States, in 2012.

THE COURT: So is Mylan acknowledging that from 2012 until July 2018, it sold contaminated API?

MR. REEFER: No, Judge. I don't think that that blanket statement is necessarily true, because, again, I'm not a process chemist, but for one, only batches where solvent was

reused would be potentially implicated in the nitrosamine -- and again, this is NDEA, it's a separate nitrosamine versus NDMA, which is sort of the July 2018 origin.

And so there are certainly instances, I believe, Judge, where if fresh solvent, non-reused solvent was used in a particular lot, you might not see any level of contamination in that particular lot, and there may be other nuances I can't explain. But no, Judge, I'm not going to, you know, concede here that every single batch from 2012 to 2018 was necessarily contaminated.

THE COURT: Thank you, Counsel.

All right, Mr. Slater.

MR. SLATER: I'm just going to clarify. The only thing we're interested in with regard to the other sartans is the manufacturing process and the test results.

We're not asking for all the other things that Mr. Goldberg listed, and, you know, the suggestion that let's wait and see what happens, Your Honor knows as well as we do and the defense knows, the depositions of their key witnesses on why did this happen by necessity, are going to go to, well, did you manufacture other similar drugs where you didn't have this issue and why? Or did you have a more significant issue?

I mean, the Court has available to it, through the defendants, samples of actual manufacturing and test results of multiple drugs, where -- variations in the manufacturing

processes, for example, what solvent was used, was it a reuse, was it new, was it DMF, and we're going -- the more information we can all have, which is in their file cabinets that shows us the various manufacturing processes and the various test results, that information is what we would depose a witness on and say, well, you have this for three years, never saw these aberrant peaks. This one, you started to see aberrant peaks. Did you ever triangulate to try to figure out, well, why are we seeing this here, why aren't we seeing this here.

And I mean, I could go down the line. Your Honor knows well what I'm talking about. This is a directly relevant questioning of these companies in terms of their knowledge, their notice, the steps they took, the reasonableness of their reactions, et cetera.

So the comparisons as between the manufacturing processes and the test results of these various drugs, which are all in the same class and is very similar, is going to be very important for the parties, for their experts and for the Court, to ultimately land on why did this happen. Because Your Honor just, you know, basically laid out, we have different manufacturing processes, we have different contaminants, but why would one happen here and not happen here, and it's helpful that we're having this open discussion here in court, but clearly, we need this information. Again,

all we want is the process and the test results.

THE COURT: Okay. Moving on, Issue No. 4, litigation hold. That's a pretty straightforward issue.

Plaintiff, is there anything to add to what you put in your briefs?

MR. SLATER: I think I wanted to just suggest to Your Honor, having read your decision in *Major Tours* a couple of times, it may be a process that Your Honor may have already contemplated, but to suggest a process to handle this in a practical way.

The first thing is that we would ask that Your Honor order in-camera production of all the hold letters from all the defendants for all the facilities that are at issue to the Court to even determine whether or not a privilege is implicated. Because there may not be information within those letters that even implicates a privilege and then, Your Honor, we don't have to talk about privilege.

You may look at these letters and say, you know what, this letter was written by the chief financial officer, it didn't come from a lawyer, I don't know. I mean, I'm giving a very simple example, but I think Your Honor has to see the letters, we can't just talk in a vacuum, No. 1.

In the interim, I think that there should be no delay in them providing the key information that we're going to need, without production of the letters, they can give that

information, and one of the things that we need to know is the dates, when were the letters issued by each party, to which facilities, and to which -- by each defendant, No. 1, we have to know the dates, and I'm reading *Major Tours* because Your Honor drew the inference in that case, that because of the delay and because of the scope of who was actually notified of these obligations, there's an inference of spoliation which triggered the production.

THE COURT: But keep in my mind, in that case, that the Court was talking in the context of a case where there was evidence of spoliation.

MR. SLATER: Well, my reading of the case and I understand it when I drilled down on it and I can certainly be missing something, ultimately, Your Honor drew the inference that there was spoliation because you said, look, there's no way that relevant documents weren't destroyed when you waited, what, three or four years before you instituted this.

So there clearly had to be relevant information that was destroyed or lost.

THE COURT: Yes, but the Court -- we knew that, we knew that in *Major Tours,* we didn't take discovery to find that out.

MR. SLATER: You knew about the delay. So the first thing we need to know is the dates. There's no -- nothing privileged about the dates on which litigation holds were

issued. It's a legal obligation. We've given you plenty of law on the other side, and I'm not going to try to argue the law on whether it's privileged or not, there's obviously cases that say it's not, and say that giving an instruction is different than giving advice.

Putting that all aside, the date is not privileged, the distribution list is not privileged, again, very important. We need to know everybody that got it, because, A, did they give it to everyone that they needed to and, B, it's going to help us to identify custodians or confirm custodial lists, which is very, very important to us.

The third thing is, the description of what is supposed to be held. Very important for us, so we can make sure the scope of the instructions is adequate, for, again, reasons that Your Honor discussed in *Major Tours* and commensurate with that, the way that the terminology is used and the actual terms that are used will help to inform our understanding potentially of certain search terms, because we don't know how they described what should be preserved and then last, what did they tell people to do.

There is nothing about that that's privileged. There is nothing that is arguably privileged in that. That is basic information, it's factual information, so they should be able to provide those components to us now. They should produce the letters to Your Honor in camera to -- and make whatever

argument they're going to make as to why it's privileged.

There's nothing for us to say because we won't have seen them, and then Your Honor I think can make a decision as to whether or not the letters can be redacted and produced, whether they could be produced in whole or whether or not we just need the information that we've asked for today. I think that's a reasonable approach to this issue.

MR. REEFER: Judge, respectfully, I think the plaintiffs are putting the cart before the horse. I think Your Honor has already identified, you know, the flaw in the argument. If you look at *Major Tours,* Your Honor is correct that before the Court entered the order to produce the litigation hold, there was already evidence of the spoliation.

The spoliation doesn't relate to the failure to adhere to a litigation hold. The spoliation refers to when was the duty to retain relevant evidence in place, when was litigation reasonably foreseeable.

And so in this instance, plaintiffs have not come anywhere close to showing spoliation as that precondition to the discovery that they're seeking, Judge.

The *Bull* case out of the Third Circuit clearly lays out the four conditions, the evidence that's cited in the plaintiffs' brief is, I think from 2016 or 2017. There was no suggestion of any litigation regarding nitrosamines or Valsartan at that time. There was no recall occurring at that

time, and moreover, they haven't shown that any relevant evidence was discarded before litigation -- I'm sorry, after litigation became reasonably foreseeable.

And with respect to the counterproposal that instead of producing litigation holds, the defendants just produce all contents of litigation holds, it would -- the proposal swallows the rule, Judge. If we're going to give them the description of the scope of the hold, the recipients of the hold, when we issued the hold and, Judge, I'll represent on the record, that at least with respect to Mylan, the litigation hold was put in place by attorneys, and so --

THE COURT: Do you have any objection or do the defendants object to identifying who received the litigation holds and the dates?

MR. REEFER: Yes, Judge, I believe so.

THE COURT: Why is that not relevant and why is that privileged?

MR. REEFER: It's privileged, Your Honor, because that reflects the mindsets and thought process of the attorneys who drafted the hold. Respectfully, Judge, we are engaged in a process right now in the identification of relevant custodians. The defendants are participating in that process. We've had an in-person meeting last Friday to further that process. The information itself, we are providing. There's no need to pierce what is a privileged

document in order to get at the same information.

THE COURT: Let me ask you a question. Suppose plaintiffs are taking the deposition of Ms. Jane Doe who was the quality assurance manager for your client, and the plaintiffs ask Ms. Doe, did you receive a litigation hold letter and when.

Do you object to that question on the ground of privilege?

MR. REEFER: I don't believe so, Your Honor.

THE COURT: So why, then, can't plaintiff find out tomorrow who was sent a litigation hold and the date?

MR. REEFER: Because, again, Your Honor, it reflects the process of the in-house counsel, the lawyers in formulating that list -- it reflects --

THE COURT: But my question is, why is it okay to ask it at a deposition, but not to give plaintiff that information tomorrow? If it's privileged tomorrow, isn't it privileged at a deposition? And you acknowledge it's not privileged.

MR. REEFER: I'm sorry, Judge, I think I need to retract my prior statement. I would object, then, if that question were posed.

MR. GOLDBERG: I don't know that that question wouldn't be objectionable and I'd certainly assert it on that --

THE COURT: On what grounds? Is it privileged?

MR. GOLDBERG: I think it does reflect --
THE COURT: Why?
MR. GOLDBERG: Because that's my client and --
THE COURT: That's your client.
MR. GOLDBERG: If that litigation hold letter went from counsel to the witness, that reveals privileged communication.
THE COURT: The fact that the witness received the litigation hold letter is privileged?
MR. GOLDBERG: I would think so, yes.
THE COURT: Suppose -- suppose plaintiffs ask the witness, what did you -- did you do anything to preserve documents? Is that privileged?
MR. GOLDBERG: If the witness -- and I would instruct the witness, to the extent you can answer without disclosing privileged information, you can answer the question.
And if the witness says, you know, the only thing I did was listen to my attorney, when I got a -- says to herself, okay, that's the point. I can say -- I can make that objection. To the extent you can disclose this information without disclosing communications with your counsel, you can answer the question. Witness says, hmm, can't do that, because the only thing I did was not do anything because my attorney told me not to do anything, says it to herself.
THE COURT: So is there any way for the plaintiffs

then to find out if that witness preserved any information?

MR. GOLDBERG: Yes.

THE COURT: How?

MR. GOLDBERG: When there's spoliation, and that's what the cases said. Let them come to court when they have evidence of spoliation and then that witness needs to say, how come on the record, you told us you didn't destroy a document when you did. That's the whole point here.

We cannot let the cart get before the horse.

THE COURT: Okay. All right. Thank you. I don't need to hear anything else, Mr. Slater.

MR. SLATER: Please.

THE COURT: Okay.

MR. SLATER: 30 seconds. There's evidence of spoliation in this case. We gave it to Your Honor.

THE COURT: No, there isn't.

MR. SLATER: Where they have shredding bins and shredding machines and the FDA for both Hetero and Mylan finding that information was being destroyed.

THE COURT: But in fairness, Mr. Slater, I read, you know, I read the papers, I read the master Complaints, it's true that -- it's true that there are references in those papers to shredding and et cetera, et cetera, in 2016, maybe even in 2017, but the fact of the matter is, I'm not ruling on this issue, but I think it probably will turn out that the

trigger for litigation is when this contamination was discovered in July '18.

So if the duty to preserve did not arise until July 2018, there can be no spoliation because something may have been destroyed in 2016 or '17, and I think based on the record, it's -- it would be very problematic at this time -- I'm not saying it's impossible in the future, but at this time to argue that the defendants could foresee this litigation in 2016 and 2017.

MR. SLATER: We don't know what they foresaw yet. We will find out. We may find out that there was a litigation hold issue in 2015 because somebody was actually thinking about what could happen.

THE COURT: Maybe.

MR. SLATER: So that's why we need to know. The other thing is, I wanted to bring to your attention. There were third parties to this litigation who likely have very important information and documents. Consultants they brought in to do testing, analysis, who created some of the manufacturing processes, et cetera. Did they get the litigation hold, what did they do, et cetera. So I just wanted -- I know Your Honor knows that but I just wanted to make it clear. Thank you.

THE COURT: All right. Moving along. Let's go to the issues where defendants took the lead first, first issue,

extent of discovery regarding foreign regulatory materials and communications. Keep in mind, Counsel, the Court read the papers. I think it understands the issues.

Mr. Goldberg, is there anything you want to add to what's in the papers?

MR. GOLDBERG: This is your issue. This is foreign regulatory.

MR. REEFER: Judge, I think context is important because we're dealing under Rule 26 with both relevance and proportionality, and we've discussed at some length some of the issues with regard to the processes in the facilities, but what hasn't been mentioned is that Mylan, for example, markets Valsartan finished dose medications in 46 countries and has been -- received approval from 14 regulatory bodies.

THE COURT: Let me ask you this hypothetical. The European agency, what is it, EMA or --

MR. REEFER: Yes, Your Honor.

THE COURT: Okay. EMA did an inspection of Mylan's plant in February 2018, and -- this is hypothetical -- and discovered all sorts of problems. They are a foreign regulatory agency body. Is not that inspection report relevant to the case?

MR. REEFER: Not necessarily, Judge, no.

THE COURT: Suppose, again, purely hypothetical, suppose that inspection report says, be on the lookout for

NDEA contamination because of X, Y, Z. Hypothetical, I'm making that up.

Foreign regulatory inspection under defendants' proposal, that wouldn't be produced, right? Is that not relevant to the case?

MR. REEFER: I think, Judge, like I said, the argument is twofold. One is relevance and one is proportionality.

THE COURT: Might there be certain categories of information that are so important and relevant that they have to be produced even though they're coming from a foreign regulatory body?

MR. REEFER: That category of documents, Your Honor, would be very, very narrow. But hypothetically, yes.

THE COURT: Let me hear from the plaintiffs and I guess my question to the plaintiffs is this. The Court has and will order fulsome discovery from the FDA, no question about it. What material information might exist in foreign regulatory bodies that you're not going to get from the FDA, especially since I read in the papers, there's a sharing agreement amongst the different agencies for anything related to this recall issue, and is it really likely that any other defendants, Mylan, Teva, ZHP, whatever, would give information to the European agency that's relevant to the case that they wouldn't give the FDA. Because if the FDA has it, you're

going to get it. How do you answer that?

MR. NIGH: Well, I think very basic, I think it's important to understand that if it goes to notice, and the defendants already conceded this, if it goes to notice, that's -- those are those lines of cases where this information from foreign regulatory agencies is discoverable.

THE COURT: It's relevant.

MR. NIGH: It's relevant.

THE COURT: It may not necessarily be discoverable.

MR. NIGH: It's relevant.

THE COURT: It's relevant, but my question is what are you going to get from a foreign regulatory agency that you're not going to get from the FDA?

MR. NIGH: So when we look at the four different types of notices -- and I think it's important to understand that. First, their limited definition is when you actually discover NDMA contamination. But there are three other types of notices that we know -- contamination, that you see in contamination cases that are -- and are here as well.

It would be when you start to receive abnormal testing or customer complaints that are received, such that when you take a look at those, you could see a trend. They were -- information that had you investigated further, you could have become aware of this problem. That's another one.

Another -- so that would go to testing and/or DMF of

these other drug processes, for example, that we talked about earlier, where if another country, they're selling this to another country, the other country has the DMF for one that's not contaminated, we -- that would be important for us.

If we were to see the testing levels for one that's not contaminated versus one that's contaminated, because we can compare the two and we can see what's the difference, that would give us some insight as to how the contamination occurred.

THE COURT: Do you know how many different foreign regulatory agencies, bodies, what have you, might have hands-on contact with the manufacturer's facilities?

MR. NIGH: Well, there's at least 15.

THE COURT: Okay. And you want discovery from all 15?

MR. NIGH: Yes.

THE COURT: Now, do you -- I guess this is my question: What are the odds that there is any material relevant information that is in the hands of those 15 regulatory bodies that is not in the hands of the FDA, given the worldwide attention, given this problem.

MR. NIGH: Well, we see it all the time. I mean, I've seen it in other litigations all the time, that one foreign regulatory agency has information that the FDA doesn't have. And because there is information being shared --

THE COURT: The biggest Class 1 recall in history?

MR. NIGH: Well, this is the biggest Class 1 recall, so I can't say other cases. But I would say that when we come to information here -- and another part is, we talked about sharing. So that's 11 of the foreign regulatory agencies. But there are four that don't share. We've got China, India, Israel. They're not a part of that agreement. So just to assume if they give information to China, that that information made its way to the FDA, I think that's an illogical assumption, that the FDA is going to have all the information that China's regulatory agency has or that India's regulatory agency has.

So the other types of notice that I think are important. When you're notified that you are engaging in risky behavior that can lead to increased chance of contamination, so that would be like a violation of good manufacturing practices.

So whether or not the FDA has every single inspection report, I don't know that they do and that's something that we wouldn't know unless we were to look at some of these other -- if we had an order that said all inspection reports from the other regulatory agencies, then we would be able to see if they have the same inspections.

THE COURT: So you want the Court to order all of that to be produced even though the FDA may already have it?

MR. NIGH: Yes.

The other one would be, you know, another example with the notice, utilizing a solvent like DMF that is known in the industry to be risky and often riddled with contamination problems. This would go to the fourth notice, which is type 2. When you're first developing a drug and you have that risk assessment that takes place when you first develop the drug, that's when a lot of times here you look at the chemistry of it, and we've already seen publications already where chemists would come out with this issue and said, had they looked at the chemistry on the front end, they would have been aware that they should be on heightened alert with the potential of NDMA formulation.

Well, this is important too because this was marketed overseas before it was marketed here in the U.S.

THE COURT: Can you identify for me any specific type of document and any specific regulatory body that in your view is important to this case?

MR. PAREKH: So the three regulatory bodies that are very, very important are the regulatory bodies where the manufacturing facilities were; China, India, Israel, obviously, because they had much more hands-on inspections and ability to inspect than the FDA did.

MR. NIGH: And we don't have -- the FDA does not have a sharing agreement with those.

THE COURT: So would you be happy just getting the inspection reports?

MR. PAREKH: So let me go a little bit more. So inspection reports for those, obviously, any testing results that were communicated back and forth from those entities would be very important to have. And also the processes that they used to get approval from those bodies to manufacture these, and what they told those bodies versus what they told the FDA they were doing is also very important.

Because we've seen in other cases where -- for example, in Abilify, which we just finished, we saw that what the defendant was telling the EMA was different than what they were telling the FDA in the same type of submission.

And so until we know what they were telling these bodies, we don't know what they have. In addition to those three, India, China, and Israel, both the EMA and Canada did independent testing of Valsartan and so those results and what tests they did may or may not have been communicated to the FDA.

The other problem with saying, well, they were all communicated to the FDAs, we don't have access to what the FDA has. We have FOIA requests. We can get some information from what the FDA got from other regulatory agencies, but it's not like we can ask the FDA, hey, please produce to us everything that you got on Valsartan that you got from other regulatory

agencies. They don't -- one, it's a burden that they don't want to do, and two, they have to spend the time to redact all of that information. So at the end of the day, we get redacted documents. If we get them directly from the defendants, we don't have that issue.

THE COURT: Okay.

MR. SLATER: Your Honor, one last thing. You asked the question of what -- is there a likelihood we'll get different information.

THE COURT: Materially different information.

MR. SLATER: Yeah. And the answer is a hundred percent yes, because A, those products were being sold, I think for the most part, in other countries before the U.S. So the dates on which the interactions took place, I would say -- I'll say are close to a hundred percent and the probability is going to be different. So when was notice and when were things being discussed specifically germane to the issues in this case, it's going to be different because the interactions took place at different times, and that's going to be critical. As Mr. Parekh just said, what did they tell those foreign regulatory agencies, and was it the same or different. In the Abilify case which was just mentioned, the labels were changed for that drug, which Judge Rodgers handled that MDL, four or five years or more before they were changed in the U.S. because different information had been provided to

Europe than to the FDA. So the FDA didn't have the information and Europe said, you have to change these labels and start warning of these side effects years before they were warned of in the United States.

So there's no expectation that identical information was being provided and, in fact, there may be communications, especially perhaps in China where something was mentioned in some back and forth but there wasn't the incentive to push it years before they went to market in the U.S.

So there's very good reason to produce these documents. The burden -- you haven't heard anything to establish a burden. Relevance has already been established and agreed to. So we need the documents that Your Honor believes and we've defined what they're most important, inspection reports, purity, testing. That's what we need to know. And when I say "purity" --

THE COURT: What's purity?

MR. SLATER: Bioequivalence. Purity has to do with whether there's contamination or not. Because again, there may be findings on tests that are not labeled as this is what this is, but they're aberrant and they require investigation.

THE COURT: Okay. No. 2 is done.

No. 3, the extent of discovery regarding each applicable defendants' finished dose manufacturing process. Anything you want to add to the papers?

MR. RUBENSTEIN: No, just that, you know, we're not trying to say that any --

THE COURT: I'm sorry, I skipped an issue. I apologize. We'll get there.

MR. RUBENSTEIN: Okay.

THE COURT: 2, the extent of discovery regarding foreign sales, marketing, and agreements.

Defendants, anything you want to add to what's in the papers?

MR. REEFER: Judge, I think the briefs are laid out there pretty well.

The only thing I would mention, Judge, is that the stated justification that plaintiffs provide for, you know, what could be construed as a very broad category of discovery, which is foreign sales and marketing, that the retort is, well, how would we know if a customer, presumably a finished dose customer like Novartis, would have alerted the API manufacturer of an issue if we're not entitled to this very wide swath of information. And the response I would have to that is, if that's what the plaintiffs are looking for, if they would like the defendants to produce core communications from customers relating to what's referred to in the papers as aberrant spikes in chromatographs, that's something that we would be willing to reproduce, but the problem is, you know, going beyond that, there's no justification for it, there

hasn't been any stated justification for it, and so with that proviso, Judge, I think the papers lay it out there.

THE COURT: Thank you. Anything you wanted to add to that?

MR. PAREKH: Just a couple of things. One is -- I mean, we're not asking for every single piece of sales information and every single piece of marketing data. That's not what the RFPs ask for. And so, you know, the things that we're looking for are what we laid out in the brief, which is communications between either end users or, you know, somewhere along the supply chain, talking about things like out-of-spec situations where they've returned product. We know that that happened. We don't know who that happened with, because that information is redacted, and if they happened to be foreign customers, according to defendants' position, we don't get any of that. I mean, their position in their brief. They stated a different position at this point, saying that they will provide some of that. But we need to be able to pin that down.

The other aspect of it is we also need to know what the process differences are between some of these customers. For example, the process that was used for sale to customers in Japan, specifically, required one extra step in the solvent quenching process -- I think it's the quenching process -- that apparently resulted in an end product with no NDMA

impurity. Why was that used solely for the Japanese customer? What did the Japanese customer know that other people didn't?

THE COURT: So why are you just bringing this issue to the Court's attention now, and why wasn't this issue in the extensive letter briefs the Court received?

MR. PAREKH: It was in the letter briefs.

THE COURT: It was?

MR. PAREKH: Yes.

THE COURT: Specifically referring to Japan?

MR. PAREKH: It didn't refer to Japan. We had to do some digging to figure out that it was Japan, but I think that happened last night, and I apologize, but we did put in that a customer had this, we just didn't know that it was Japan at that point, or we missed it, and I apologize. But, you know, we know that that happened. We don't know as to other customers, whether or not they had their own specs. We believe one of the other customers, Par, actually was buying ZHP's product using Process 1 when ZHP discontinued Process 1, Par decided that we're not going to buy API from ZHP anymore. It would be really good to know why they decided that. What about their Process 2 did Par not like? What did they know? What did they communicate to ZHP about it?

I mean, these are just things that we gleaned from bits and pieces in the core discovery. We don't know what we

don't know a lot of the time. This is us trying to piece together that puzzle. That's why we need this information.

THE COURT: Issue 4, the extents of discovery regarding Valsartan testing.

Oh, I'm sorry, here we go again, I skipped one.

3, the extent of discovery regarding each applicable defendants' finished dose manufacturing process. Back to Teva.

MR. RUBENSTEIN: Right. So, you know, we're not saying that documents are wholesale barred from the finished dose manufacturers. You know, things like the API testing, the certificates of analysis, quality complaints, they would clearly be discoverable, but in terms of the actual, you know, nuts and bolts converting, formulating the API from the API into the finished dose pill, you know, they've asked for documents identifying, you know, patented machinery that was used and, you know, all the external excipients and inactive ingredients, things like that that were used. You know, that's clearly irrelevant, overly burdensome, you know, not going to lead anywhere.

You know, we keep talking about inspection reports and things like that. So, you know, these manufacturing facilities for the finished dose, they make dozens if not hundreds of products. So if there's an inspection report or an observation about a product that's completely unrelated to

Valsartan, we don't see why that that's relevant because, you know, it's not connected to Valsartan or, you know, detection of impurities or anything like that. So we don't see how something like that would be relevant if it's, you know, about a completely different drug, because like I said, these facilities make dozens if not hundreds of different products.

So, you know, we're just trying to reign in the scope here. You know, clearly, there's going to be some things that are discoverable but clearly there's -- requests they are beyond the pale.

THE COURT: You're not taking the position that all discovery regarding the finished dose manufacturers is off limits --

MR. RUBENSTEIN: No.

THE COURT: -- it just has to be focused and relevant to the case.

MR. RUBENSTEIN: Correct.

THE COURT: All right.

Plaintiff?

MS. HILTON: Your Honor, if I may, I'm glad to hear that the finished dose manufacturers are committing to some production, but, you know, first of all, I think, you know, I need to make the point that API manufacturers in this case are also finished dose manufacturers and so they have taken the position that they are some separate and silent entity and,

therefore, not required to do the same amount of discovery in into their finished dose practices as a Teva or a Torrent or an Aurolife. So that's our first issue here. We want to make sure that both the API manufacturers are going to commit to the same level of discovery of their finished dose facilities, as the finished dose manufacturers, because API manufacturers are finished dose manufacturers.

So, that's sort of like a -- we have a schism up there, and so that's something that, you know, we sort of seek the Court's --

THE COURT: Correct me if I'm wrong, but I was assuming that although it may be one facility, the API manufacturing and the finished dose manufacturing are segregated.

MS. HILTON: They are, Your Honor.

THE COURT: So, it's not like if the FDA comes and does an inspection, they necessarily will do both at the same time. They might do one and not the other. That was my assumption, I don't know, but it's not like it's one -- maybe I'm wrong. I didn't assume it's one big room where everything is done finished dose and API manufacturing.

MS. HILTON: You're correct, Your Honor, but the -- you know, I'll state this, finished dose manufacturers in core discovery produced establishment inspection reports for their finished dose manufacturing facilities.

API manufacturers are of the position that they are not required to produce this discovery at all.

And so this is the schism we have. So we're trying to seek a commitment that first of all before we decide what finished dose manufacturers are going to produce, that API manufacturers are going to fall in line with what the other finished dose manufacturers are producing when we decide what that scope is.

THE COURT: You want it to be coextensive? In other words, whatever the API produces, the finished dose produces?

MS. HILTON: No, I want it to be whatever the finished dose produces, the API produces. Because the way that -- you know, my understanding of it is, and like everyone in this room, I'm not a process chemist, but, you know, the API is made in one facility. It is then shipped to another facility where it is tested, you know, you go -- stability testing, the chromatography, it is then manufactured in a pill and then distributed, right? API manufacturers, as I understand it, and they can surely correct me if I'm wrong, are saying that they are only going to produce documents related to the API and not what happens once the API leaves and arrives at their finished dose facilities, whereas the finished dose manufacturers, Teva, Torrent, Aurolife, have comitted to producing documents at these finished dose facilities, and so that's the schism that we find ourselves

in.

THE COURT: Okay.

MS. HILTON: And that's just -- that's just the larger issue, but we also have issues of what the finished dose manufacturers would produce, which is to say, you know --

THE COURT: What do you want?

MS. HILTON: Well, first of all, with respect to -- you know, I was a participant in the request for production, the meet and confers on manufacturing. You know, surely at this point in time, like you've said, can't commit to what we don't know, what we don't know happens at the finished dose process, but there are key documents that we can receive.

THE COURT: Such as?

MS. HILTON: Such as establishment inspection reports that list all of the exhibits that are provided by the finished dose manufacturer.

THE COURT: What else?

MS. HILTON: Quality assurance documents, standard operating --

THE COURT: Wait a minute. See, quality assurance documents, you want to know if it's the right color or the right size or the right weight?

MS. HILTON: I think when I say "quality assurance documents," you know, we want to know specifically, and I'm not limiting it to this, but we want to know what they are

going to do when they receive the API, what is the testing protocol for that, what is the model testing protocol, what are they supposed to do when they notice an aberrant peak with respect to the API. Are those testing protocols validated. All of these things go to, you know, back to the issue of Novartis. How did Novartis identify a problem when all of the defendants did not?

And so that's sort of -- that discovery will help inform upon whether there is some aspect of the finished dose manufacturing that may be implicated. But we need to see those deviation reports, we need to see, you know, those out-of-spec testings and out-of-trend testings before we can make a determination as to, you know, whether we don't need X, Y or Z, and that's what we told the defendants in our meet and confer, with respect to the API manufacturing, too. We have to understand where the problems are being presented before we can start limiting.

THE COURT: Okay. Next. Extent of discovery regarding Valsartan testing. There is no issue regarding the -- pronouncing it right, chroma --

MR. GOLDBERG: Chromatography, Your Honor.

THE COURT: Chromatography. Is there an issue with bioequivalence?

MR. GOLDBERG: I don't think there is. I just think when it gets to chromatography, chromatography could be used

in different ways and what we're talking about, where we think the focus should be is with respect to impurities, like nitrosamines and potentially residual solvents, because we're using a solvent, Mylan is using a different solvent, but that should be where the chromatography testing focuses and then the bioequivalence to the extent it hasn't already been produced, and mind you, most of it's been produced because that is in the DMFs and what we communicate with the FDA on. But that's where we think it should be.

THE COURT: Plaintiffs, is that a good place to start?

MR. WILLIAMSON: Well, that's a good starting point, Your Honor, but I believe that, again, we don't know what we don't know. What we would like for the defendants to do is to produce a list of all of the testing that is performed at their facilities. We can then take the list to our experts and have our experts review and tell us whether they believe in addition to what they've already agreed to give us if anything else is relevant and we can meet and confer with the defendants and if we both agree, then there'll be productions. If not, we can come back to Your Honor on December 11th or whenever you advise us to do that and we will say, Your Honor, we need X, Y and Z because of this.

THE COURT: Got it.

MR. GOLDBERG: Your Honor, just one point on that

list. We produced, and I'm sure it's with the other manufacturers, a list of the kinds of things we test for. It's not a mystery. This is Page 9782 of Prinston's production. They have experts. Their experts should know if testing about appearance or solubility or identification are things that would bear on testing about impurities. So that list is there.

THE COURT: All right. With regard to this list, and we're getting to the end, 7 and 8, I, Court, understands have been -- are agreed upon. So the last issue, and I'm glad we're saving it for last and then we'll take a break, is the relevant time period for the custodial search, and I've already confessed that this is the issue the Court needs help with.

I think a good place to start is let's, for each defendant that we're talking about, find out what the proposal is from each side.

So Mr. Goldberg, ZHP, what are you proposing?

MR. GOLDBERG: Your Honor, ZHP proposes that --

THE COURT: Just give me the date.

MR. GOLDBERG: Sure.

THE COURT: And then we'll come back to argument.

MR. GOLDBERG: I would say January 1st, 2015 for general custodial discovery with respect to the document request and how the Court rules as to those things. With

respect to manufacturing specific questions, questions about chromatographic testing, about impurities, bioequivalency, to the extent we can be specific and go back in a manufacturing process, we acknowledge that we have made a change in December 2013, we acknowledge that change started in 2011, and if there are specific questions about the process even before 2011 -- granted, it should be very specific as to the pertinent issues, we think we can go back there. But for general discovery, January 1, 2015, because any of our API only could have been sold in the U.S. after that point in time.

THE COURT: Plaintiff, we'll start with the date, we're going to circle back to the argument. What date are you proposing?

MR. HONIK: Your Honor, the date we propose coincides with the first Drug Master File application, would be September of 2007, and in point of fact, certain of the questions we've propounded or requests for documents predate that.

And the reason that we've done that, if you want to hear a little argument on that.

THE COURT: Can we come back to argument?

MR. HONIK: Yes, we can.

THE COURT: I just want to get this list.

Mylan, what are you proposing?

MR. REEFER: Judge, we propose September 21, 2012, the date that the first finished dose product was approved by FDA for market in the United States, with the proviso that in core discovery we all be produced three ANDA files and the DMF, which sheds light on the process development issues.

THE COURT: What are you proposing for Mylan, plaintiffs?

MR. HONIK: Your Honor, let me just point out something generally for each of these. The answer in every instance is whenever their research and development began related to their manufacturing process. In the case of API, when they did the research that led to their submission of their Drug Master File.

In Mylan's case, they did that in August of 2006, and that's not a hard cutoff and we need to articulate that the starting date in our mind is when the run-up to that occurred, when they were doing research and development activities -- and this is true for all the defendants, whether finished dose or API, where they were deliberating on the choice of a solvent, the choice of catalyst, the risk benefit profiles, inspecting, for example, the patent that Novartis had as the innovator. All of that consideration that the defendants had is directly germane to the issue in this case and nothing exemplifies it, frankly, more than the ZHP example that Mr. Nigh spoke to earlier.

I have may engendered some confusion by using the term "DMF" because there's DMF solvent and there's the Drug Master File. And what I had meant to convey -- and this is very important to illustrate our thinking about the timeline here.

In 2007, when they first received approval for Process 1, which did not use DMF, they had no problems with contamination. Lo and behold, with the beginning of Process 2 in 2010 and then the second iteration of that, in both instances, they did have a problem.

Our experts need to understand why they didn't have a problem with Process 1, which in ZHP's case goes back to 2007 and understand what their research and development told them in the run-up to that, about that process, which was apparently a good process, it didn't produce impurities.

So, what I'm getting at is I can tell you, when they either put in their ANDAs or put in their DMFs with FDA, but we think with respect to those processes, we need to have the research and development that led up to that. So I can give you the date, but in point of fact, we want the period that led up to that as well.

THE COURT: So I wrote down August 2006, but you may want earlier than that.

MR. HONIK: Yes. And our request for production is specific. So in the handful that we focus on around the ANDA

filing, we are specific and use words not dates to suggest that we want your research that led up to certain components of their ANDA filing, because that's their representation to the regulatory body saying, this is how we want to make this pill, this is the possess we want to employ, these are the quality controls that we want to use and we -- and our experts need to understand what that was, what their thinking was, what the basis for that approval was.

THE COURT: I got it.

MR. HONIK: So long-winded way of saying, yes, the ANDA filing for Mylan was August of 2006.

THE COURT: Teva, what's your proposed date?

MR. RUBENSTEIN: So, the first time that Teva ever sold a Valsartan drug in the United States was March of 2013, and we propose to go back to January 1st of 2013 for the run-up to the launch for whatever testing of API for the product that was going to ultimately be sold would have been happening.

THE COURT: And plaintiff?

MR. HONIK: Teva was a second filer. In January of 2005 they did a ton of research and development with respect to that Abbreviated New Drug Application.

THE COURT: Got it.

MR HONIK: But we'd like to see the run-up to that as well.

THE COURT: Torrent?

MS. NAGLE: Torrent proposes January 21st, 2014, which is a few months prior to the first time that Torrent sold Valsartan in the U.S.

THE COURT: And plaintiff as for Torrent.

MR. HONIK: Their ANDA filing was in June of 2009 and we'd like the run-up data and research on that as well.

THE COURT: Okay. Is there a party Aurolife.

MS. HEINZ: Yes, Your Honor.

THE COURT: Sorry, I forgot all about you today.

MS. HEINZ: No problem. Jessica Heinz.

We took the position that the relevant time period is March 21st, 2013. That's when our first ANDA was approved by the FDA for a Valsartan product.

THE COURT: And plaintiffs' date for Aurolife?

MR. HONIK: Your Honor, we have yet to receive any discovery regarding Aurobindo Limited and thus we don't know the date on which the Indian entity filed its DMF for Valsartan API. So we don't know with any degree of certainty, but at a minimum we should begin at sometime prior to June of 2010, certainly. And that's the date by which the U.S. entity submitted their ANDA submission to the FDA. But it could be earlier.

THE COURT: Okay. Let's circle back.

Is ZHP now -- you're proposing general custodian

January 1, 2015 testing, may go back to 2013 or 2011. The 2015 date, that is what?

MR. GOLDBERG: That's triggered by the ANDAs that were -- the ANDA that was approved for our finished dose and that the API that we supplied was approved with the ANDAs. Like Torrent's ANDA happened in 2015.

So any of our API could only have been sold in the U.S. after January 1, 2015.

THE COURT: But before that, ZHP was selling API around the world?

MR. GOLDBERG: Not in the U.S.

THE COURT: When did it start selling API around the world?

MR. GOLDBERG: That, I don't have the answer to now. I can certainly get that to you.

THE COURT: Do you know, plaintiffs? But plaintiffs are saying that it was --

MR. HONIK: We don't know the precise date. I presume it predates 2007.

THE COURT: That's what I was going to say. At least as to --

MR. HONIK: At least as far back at 2007.

THE COURT: Okay. And the plaintiffs propose September 2007 because that was the date of the first DMF --

MR. HONIK: Correct, to the FDA.

THE COURT: Okay. And Mylan is proposing September 21, 2012, because that's the date of FDA approval for sale in the U.S.?

MR. REEFER: Correct, Your Honor.

THE COURT: Were they selling finished dose Valsartan somewhere else before that date?

MR. REEFER: I don't know, Judge, frankly.

THE COURT: But you want, plaintiff, August '06?

MR. HONIK: Yes, sir.

THE COURT: Because -- at least August '06 because the problem --

MR. HONIK: That's when the ANDA filing occurred.

THE COURT: Teva, January 1st, 2013, that's a little before the start of actual U.S. sales?

MR. RUBENSTEIN: Correct.

THE COURT: And when was ANDA approval?

MR. RUBENSTEIN: In May of -- I'm not exactly sure.

MR. HONIK: The ANDA was substantially completed January 7th, 2005.

MR. RUBENSTEIN: But that's not when it was approved.

MR. HONIK: That's when it was substantially completed, where the approval is largely irrelevant, but the work that Teva did in supplying the information to the FDA was complete by 2005.

THE COURT: So let's use Teva as an example. The

parties are disputing whether discovery should be produced between January '05 and January 2013. That's a long time. That's eight years. What are you looking for during that eight years that wouldn't be produced if we used the start date as January '13?

MR. HONIK: We would be losing all of the information that Teva researched and developed in evaluating the process for making the pill that they put into this marketplace.

We know, because of the process of building into an ANDA, that the company invariably had to do extensive evaluation of processes and evaluation of, for example, the innovator patent. All of that is spadework that all of these companies do in the run-up to it.

And so if it's true what Mr. Goldberg has suggested all along, that this is about the manufacturing process, the choices that were made surrounding that, the solutions that were employed, the solvents that were employed, we need to understand the thinking that went into the company's choices and the thing that would most reveal that to us, as far as we can see, would be the support for their Abbreviated New Drug Applications.

THE COURT: So suppose, hypothetically, when we identify the custodians for Teva, I don't know how many, let's just pick a number, 10, out of X number, people who worked in the laboratory and the quality control department, you're

saying to Teva, because we want to know how you developed this manufacturing process back to January '05, these people who had nothing to do with that, we're going to search eight years worth of their records. Right? Because you want January '05, Teva wants January '13 and that's eight years. You're interested in the manufacturing process. Suppose these quality assurance people and laboratory people who had nothing to do with the manufacturing process, you're saying to Teva, they have to search those eight years of records?

MR. HONIK: Well, if I understand the hypothetical, Judge, it will be self-limiting because we're going to agree separately to search terms, and if under your hypothetical they've had nothing to do with it, then nothing will come up.

THE COURT: No, nothing will come up, but they still have to search.

MR. HONIK: But your hypothetical says -- we're talking about these 10 custodians, right? And we're going to agree at some point, or the Court will direct appropriate search terms and the question is how far back do you have to go in the database.

THE COURT: Exactly.

MR. HONIK: And, yes, I would -- I want them to go back to the point in the company's history when it was weighing and considering all the options about how they were going to manufacture this bill and it will be self-limiting if

indeed one of the ten, in your hypothetical, if he or she doesn't have anything in their cache of data, then nothing will come up.

But the question it seems to me is, should we have the right to ask to go back. Is there some factual basis that supports the idea that going back to this more distant point in time -- I understand it's eight more years, it's not an insignificant period of time. Is there a basis to suggest that there may be something there that is germane, if not in this custodian, then in that custodian. And because we know in the run-up to an ANDA filing, not when they launched, but in the development prior to the launch, that is -- we know it from many cases reveals a great deal of their internal thinking and weighing, should they use Process 1. What's the reason that Par said, we don't want the DMF solvent process, we want the other process.

We know that much in this very case. Are there other customers, are there other experiences that these finished dose manufacturers have that inform the way they elected to support their ANDA.

It's relevant to go back and if there are no documents, or it's -- you know, it will be self-limiting.

MR. SLATER: Can I just add one thing to that? Specific example. During the process of developing these manufacturing processes, they had to consider, for example,

solvents. They had to evaluate which ones we're going to use. Are we going to use reused solvents? Are we going to use new solvents? What are the risks? What is the quality assurance evaluation? Because, for example, we know a lot more about CHP at this point, because we had that meeting. What was quality assurance's role in this? What did they find? What did they say; what were their concerns?

I mean, the whole run-up is their body of knowledge that leads up to where we get to. It's not like at a fixed point in time everything starts. It's not like a baby is being born. This is a process where it was being constructed for years and years and their process is going to be relevant, and it's clearly relevant, it's clearly very significant because when we depose these witnesses, obviously we're going to say, well, what went into this decision, and are we going to get objections, you can only go back to 2013, January 1st, even though the decision was made based on information they've developed for six or seven or eight years before that. That would be inequitable and I think it would cut us off from very, very directly relevant evidence.

MR. HONIK: So to use a metaphor that Ms. Goldenberg used last night, she said, the baby's baked by 2013, the baby's baked. And so we need to go back in this case, in Teva's example, to 2005, when the baby was starting to be created.

MR. RUBENSTEIN: Your Honor, if the ANDA file was submitted in 2005, to the extent there were any changes between 2005 and March to that ANDA file, that would be in the FDA correspondence with respect to that ANDA file, which the plaintiffs have.

So, you know, I don't know what they're talking about all these different solvents that need to be considered. That's not in the finished dose product. And, you know, quite frankly, all that really matters is what did they come to market with. Not always considered seven years before they came to market. What did they sell on the market?

MR. HONIK: Here's a perfect Teva example, and I was reminded of this. Teva at one point in time bought a pharmaceutical entity called Cobalt, C-O-B-A-L-T, who bought ZHP API. They specifically requested Process 1 when Process 2 was in place. They refused to take Process 2 for reasons we suspect having to do with impurities associated with that process.

That's a Teva entity. If the Court cuts this off at 2013 or something close in time that's arbitrary, we will miss that sort of judgment making on the part of Teva, a defendant in this case.

There's a reason their predecessor company which they acquired requested Process 1, and if we have an arbitrary cutoff that postdates that decisionmaking, it will never be

revealed to us. And if it's true, as Mr. Goldberg has said time and again, it's about the manufacturing process, the decisions and choices that these companies made around it, we need to pull back the curtain and understand their thinking about it.

MR. RUBENSTEIN: And, Your Honor, that -- I mean, that might be a specific example, but I don't even know that that relates to the ANDA that was filed in 2005. That could have been a different ANDA, which I believe it was.

So, I mean, you know, coming up with these hypothetical situations doesn't justify Teva having to go back an additional eight years, find all the different custodians that there could have been during that eight-year time period, you know, just to pull a rabbit out of a hat, basically.

THE COURT: Got it.

Torrent, January 1st, 2014, can you refresh my recollection about why you picked that date?

MS. NAGLE: Sure, Your Honor. That date is a few months prior to the first sales of Valsartan in the U.S.

THE COURT: And I have defendant -- I'm sorry, plaintiff at least as early as June 2009.

MR. HONIK: That's correct.

THE COURT: And last but not least, Aurolife, could you refresh my recollection about May 21st, 2013.

MS. HEINZ: Yeah, it was March 21st, 2013.

THE COURT: I'm sorry, March 21st.

MS. HEINZ: That was when the FDA approved our first Valsartan product for sale in the U.S.

THE COURT: When was FDA approval of Torrent? You gave me the sale date. What was the FDA approval date?

MS. NAGLE: I'm not quite sure.

THE COURT: It had to have been earlier than that, right?

MS. NAGLE: Yes.

THE COURT: All right.

MR. HONIK: Your Honor, it was pointed out to me that we missed or haven't thus far discussed Hetero or Camber from whom we have --

THE COURT: Oh, are they finished dose people, too?

I know Hetero and Camber -- well, I thought Hetero wasn't served yet.

MS. HILTON: That's the U.S. entity, Hetero USA, which is served, which is represented and acted as the regulatory U.S. agent for Hetero Drugs, Hetero Labs.

THE COURT: That reminds me of an issue. The FDA liaison issue, is that what they are?

MS. HILTON: Yeah, they are the registry agent, they're the liaison.

THE COURT: And they're taking the position that they're not an API manufacturer or finished dose manufacturer.

MS. HILTON: Correct, and there Camber is a similarly situated entity. It is taking the position that it is neither a manufacturer, but it is the distributor of the product, the seller of the product in the United States.

THE COURT: Distributors are a different category, we agree. I think we're going to finalize that in January, but --

MS. HILTON: Correct. But distributors, as to, like a McKesson or a Cardinal, is, to us, to plaintiffs, is a different type of distributor than a vertically integrated U.S. arm that sells drugs to McKesson and Cardinal.

THE COURT: Let's put them in the same category.

How many different FDA liaisons do we have in the case besides Hetero?

MS. HILTON: Huahai U.S. is in this case.

THE COURT: I'm sorry?

MS. HILTON: Huahai U.S.

THE COURT: Well, we're dealing with that.

MS. HILTON: I think Hetero USA is the only one --

THE COURT: So what do you want from them that you don't have?

MS. HILTON: Well, you know, first of all, I think we have basic agreement, but we believe that we should be selecting custodians for these entities and we believe.

THE COURT: Have you started yet?

MS. HILTON: We've sort of started the process.

THE COURT: Can we put that until January? Because that would open up a whole new door. I should -- if I had to do it again, I would put that on the macro issue, what to do with the FDA liaisons, but we didn't. Can we save that for January? I think we have our hands full with the API and finished dose people. Okay?

MS. HILTON: Yes, Your Honor.

THE COURT: All right. Before we break for lunch -- when we come back from lunch, 2 o'clock, you'll get the Court's oral opinion on all these issues, then we will meet with Judge Kugler. Any other issues you want to address now?

MS. GOLDENBERG: Yes, Your Honor, issue No. 5 from the defendants' brief that we didn't cover, relating to other adverse health effects.

THE COURT: Oh, did I skip an issue? I'm sorry.

MS. GOLDENBERG: We did. I think we can keep it pretty quick.

THE COURT: Okay.

MS. GOLDENBERG: Here's what we want, so we'll start with that.

THE COURT: How refreshing.

MS. GOLDENBERG: We want information, of course, pertaining to cancer and I think we're on the same page about that.

THE COURT: Are we talking about about from day one or after the contamination was discovered?

MS. GOLDENBERG: No, from day one, Your Honor.

THE COURT: See, here's the problem. How do we deal with this? They're a drug company. Clearly, they had to do health tests on whether this drug causes heart problems, probably cancer. You want -- I mean, that's not relevant to the case, is it? You want to know health effects related to the contamination.

MS. GOLDENBERG: Well, here's why it's important because I think we all remember from our previous case management conference where we saw a very long list of conditions that the defendants gave is that they're going to use to defend as specific causation. So this issue, really on the personal injury side, it relates to specific causation, and on the class action side, it relates to bioequivalence and the benefit of the bargain. So on the specifics causation side, if the defendants are saying, look, the only injuries in this case are cancer, we're on the same page, then we need that information.

But beyond that, they're going to say to our clients, were you ever exposed to wood or kryptonite, as we joked last time. But to the extent they have any information about anything that they've put on the plaintiff fact sheet causing cancer, we should be entitled to that information.

THE COURT: So you want to know, like, when they were developing Valsartan, whether they investigated whether it causes cancer?

MS. GOLDENBERG: Not whether Valsartan causes -- well, I mean I would think that they would, but if there's information that they have about the drug or any of the contaminants causing cancer, precancerous condition or injury to any of the organs that we have talked about, digestive tract, then that's going to be important.

The other --

THE COURT: Okay. So right now, we're just dealing with health effects of exposure to NDEA NMBA, whatever it is, right? You want to know that, basic?

MS. GOLDENBERG: Right, that's one thing we want to know.

THE COURT: Okay.

MS. GOLDENBERG: On the class side, what we've seen on Page 4 of the defendants' brief is a heading that says Valsartan was the active pharmaceutical ingredient contained in a safe, effective and life-saving heart medication.

So now we have a defense that we have to rebut that says Valsartan is going to save lives, right? That's what they're going to get up and say to the jury, that this drug saved our clients' lives and if they hadn't taken it, they would have suffered some other type of health problem.

So on the class action side, there are going to be arguments about efficacy and whether or not the drug actually does its job. And when it's contaminated with --

THE COURT: But that's not what this case is about.

MS. GOLDENBERG: Well, as a personal injury lawyer that's not what my case is about, but on the class action side, I think we are going to see that defense.

THE COURT: In terms of discovery, this case isn't about the health effects of taking uncontaminated Valsartan, is it? That's what you want.

MS. GOLDENBERG: We want uncontaminated Valsartan, absolutely.

THE COURT: No, no, no. You want discovery regarding the health effects of uncontaminated Valsartan.

MS. GOLDENBERG: We want discovery about the health effects of contaminated Valsartan.

THE COURT: Yes, I understand -- that, I understand.

MS. GOLDENBERG: Sure.

THE COURT: What else do you want?

MS. GOLDENBERG: Adverse health effects about cancer, anything the defendants asked about in the plaintiff fact sheet, precancerous tumors or mutagenic diseases or disorders, and then anything relating to injuries to the digestive system that's implicated by taking Valsartan.

THE COURT: Whether or not it's contaminated.

MS. GOLDENBERG: Yes.

THE COURT: Okay. I don't think I need to hear from the defendants. Any other issues we need to address before lunch? Okay -- one more.

MR. PAREKH: Sorry. One item is just in their issue No. 8. The submission by defendants is not quite right and I just want to make sure that we have the agreement that we've actually reached on the record, which is the agreement regarding the translation of foreign language documents, is that -- and you can correct me if I'm wrong, but it's our understanding that any translations that were created by defendants for reasons other than this litigation, that is, translations created during the normal course of business will be provided to us with the translated document. It's only translations that were created for purposes of this litigation that will be withheld.

THE COURT: I think that's fair.

So let me see if I can put that down in language, because I think that's important to be documented. Translations in the -- translations not specifically done just for this litigation?

MR. PAREKH: Correct, Your Honor.

THE COURT: Okay. I would assume, I don't know, that when they made submissions to the FDA, they had to be in English?

MR. PAREKH: Yes, there's definitely translated documents.

THE COURT: So someone translated Chinese too.

MR. PAREKH: Absolutely. And we just want to make sure that there's no miscommunication as to what is and isn't produced.

THE COURT: Okay. Any problem with that, defendants?

MR. GOLDBERG: No, You Honor. We have agreed any documents that have been translated in the normal course of business will been produced and they have been.

THE COURT: Okay. So we'll be back here at 2 o'clock, you'll get the Court's rulings and then we will meet with Judge Kugler. Unless something unforeseen happens, I don't foresee that meeting with Judge Kugler being very long, but I asked Judge Kugler to be available, because, you know, frankly, you haven't seen Judge Kugler for a couple of our last meetings and maybe there's issues you want to address with him, so you'll have your opportunity to do that.

Thank you. We're adjourned.

THE DEPUTY CLERK: All rise.

(12:57 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Karen Friedlander, CRR, RMR
Court Reporter/Transcriber 11-22-19/Date

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